# THE EFFICACY OF A HOMOEOPATHIC FLU COMPLEX (ARSENICUM IODATUM, GELSEMIUM SEMPERVIRENS, EUPATORIUM PERFOLIATUM AND FERRUM PHOSPHORICUM) IN THE TREATMENT OF INFLUENZA TYPE SYNDROME.

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I, Raakhee Gunvant Mistry do declare that this
dissertation is representative of my own work.

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# DEDICATION

To my parents Mr and Mrs G. Mistry who gave me the love,

support and motivation I needed

to complete this course.

&

Mr D.K. Bhana and family of Durban

who allowed me into their home

and their hearts

during my six year stay in Durban.

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# ABSTRACT

The purpose of this investigation was to evaluate the effect of a homoeopathic flu complex consisting of Arsenicum album, Gelsemium sempervirens, Eupertorium perfoliatum and Ferrum phosphoricum in the treatment of influenza type syndrome in terms of the patient's response to the treatment and the patient's oral temperature.

It was hypothesised that the flu complex would reduce the severity and duration of symptoms in patients suffering from influenza type syndrome in terms of the patient's response to the treatment and the patient's temperature.

This complex was formulated in the 30th potency by Dr Bloch and Dr Lewis of Cape Town, who have had much success using it in the treatment of influenza type syndrome, especially where no clear symptoms were present on which to prescribe. The remedies in the complex are often individually used to treat 'flu',with good results.

This study was a double blind randomised, placebo-controlled investigation. Convenience sampling was used to select 30 patients of both sex and between the ages of 18 and 60 years, from the greater Johannesburg-Pretoria area. Patients had to have an oral temperature of 37.8°C greater and had to experience influenza like symptoms of ≤ 24 hour duration.

Half the patients received placebo and constituted the control group. The other half received the homoeopathic complex and constituted the experimental group.

Patients completed a questionnaire on day 1, 3 and 5 of the study. During the five day trial period, patients recorded their oral temperatures twice daily (morning and evenings). Physical signs were assessed and oral temperatures were recorded by the researcher on days 1, 3 and 5.

Non-parametric tests were used to make statistical analysis. Intergroup comparisons for the parameters measured were made using the Mann-Whitney unpaired two-tailed test at the $\alpha$=0.05 level of significance.

There was no significant difference in improvement between the placebo and treatment group in terms of systemic affections, physical findings and oral temperatures recorded by both the researcher and the patient. The only significant difference noted was in the respiratory affections at the second consultation.

Intragroup comparisons for the parameters measured were made using the Wilcoxon's signed rank test at the $\alpha$=0.05 level of significance. Improvement was shown within both the placebo and treatment groups in terms of systemic affections, respiratory affections, physical findings and oral temperatures recorded by both patient and researcher.

The statistical analysis revealed that the homoeopathic flu complex tested did not reduce the severity and duration of influenza type syndrome in patients when compared to the placebo group.

The results of this study confirm the basic principle of homoeopathy which is: like cures like. A remedy will only work if the symptoms it produces in a healthy person matches the symptoms of the ill person for whom it is being prescribed. A complex consisting of remedies covering the specific symptoms of the 1998 influenza epidemic may have revealed more promising results. A mixture of remedies designed to cover a condition instead of the symptoms the patient presents with, may not necessarily produce amelioration of the condition.

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# CHAPTER ONE

## INTRODUCTION

Outbreaks of influenza have been recognised since ancient times and are responsible for devastating global morbidity, death and economic loss. The characteristic epidemiological features of influenza include the occurrence of frequent but unpredictable epidemic and periodic world-wide pandemics. (Wiselka 1994.)

Each year, in the United States, an estimated 13.8-16.0 million influenza related respiratory illnesses occur in individuals that are younger than twenty years. For older individuals the estimated frequency is 4.1-4.4 million influenza related respiratory illnesses per year. (Monto 1995.)

Conventional treatment for influenza is mainly prophylactic in the form of annual vaccinations (Houck et al. 1995). However in a study conducted by Libow et al. (1996), in a Jewish nursing home, it was found that the vaccine had no effect on the incidence of influenza-like illness or the associated death rate.

Amantadine hydrochloride and rimantadine hydrochloride have also been shown to be effective in prevention and treatment of influenza infections. Both these drugs have been linked to severe side effect especially in the elderly. (Arden et al. 1996.) Naturally occurring influenza A viruses which are resistant to both amantadine and rimantadine

have also been isolated (Houck et al. 1995). A safer, more effective therapy is necessary for influenza treatment.

According to Savage (1984), orthodox medical treatment has very little to offer when it concerns virus infections. He further adds that while the search goes on to find specific anti-viral preparations which are free from side effects, homoeopathy could be effectively used to treat patients.

Homoeopathic treatment acts together with the body's reaction and is based on the 'similimum' principle, that is the use of infinitesimal concentrations of drugs which have the ability to induce in healthy individuals, symptoms similar to those presented by sick persons (Jouanny 1993:13-15). The problem with similimum, in acute conditions, is that patients often do not present with clear symptoms on which to prescribe. A school of thought soon developed where certain diseases, especially some acute diseases, were treated with substances or drug mixtures tailored to the disease characteristics alone. (Ferley et al. 1989.)

Porter (1995) found that homoeopathic oscillococcinum was beneficial in treating influenza type syndrome, but this medicinal substance was chosen because of its anti-viral properties and the symptom picture, the patient presented with was not taken into account. A study to determine the efficacy of homoeopathic similimum on influenza type syndrome is currently being conducted by Maharaj, (personal communication 1997).

The individual remedy components of the complex investigated in this study, cover the major characteristics of influenza type syndrome. The complex includes:

- Arsenicum iodatum which is recommended for influenza with persistent, irritating corrosive discharges (Vermeulen 1994:53);
- Gelsemium sempervirens which is recommended for influenza of the encephalitic type where there is painful cephalic congestion with dazedness (Jouanny 1993:156);
- Eupatorium perfoliatum which corresponds to stiffness with soreness and a sensation as if the bones were breaking (Jouanny 1993:147);
- Ferrum phosphoricum which corresponds to inflammatory conditions accompanied by a low fever and a tendency towards localised congestion or haemorrhage (Jouanny 1993:152).

The above complex has been formulated in the 30th centicimal potency and successfully used to treat influenza type syndrome by Dr Ruth Bloch and Dr Barbara Lewis of Cape Town, but no planned clinical trial had been conducted to date, (personal communication 1997).

These drug mixtures are gaining popularity among large sections of the medical profession and among the public, who can buy them over the counter. These preparations also provide the opportunity to design conventional trials in a way that has not so far been possible with regular simplex remedies. (Ferley et al. 1989.)

The purpose of this placebo controlled investigation is to evaluate the efficacy of a homoeopathic complex consisting of Arsenicum iodatum, Gelsemium sempervirens, Eupatorium perfoliatum and Ferrum phosphoricum, in the treatment of influenza type syndrome in terms of the patient's response to the treatment and the patient's oral temperature.

This study attempted to provide a quicker alternative to the similimum in treatment of influenza type syndrome especially in cases where clear symptoms are unattainable. It also attempted to provide the public with a homoeopathic over the counter influenza remedy that would be effective in treating all patients and thereby save them the cost of a homoeopathic consultation.

# CHAPTER TWO

# REVIEW OF THE RELATED LITERATURE

## 2.1 INTRODUCTION

Records of influenza-like epidemics can be found throughout history. During the past four centuries, there may have been as many as 30 world pandemics of influenza. The 1918-1919 pandemic, which was known as the Spanish flu, was estimated to have caused 20 million deaths amongst 700 million clinical cases; more deaths than the first world war. In 1957, in the United Kingdom, a new strain of the A-Hong Kong Influenza virus was responsible for five thousand deaths and the cost to the nation was more than a hundred million pounds. (Fry 1983:58-69.)

Influenza and influenza-related illnesses are responsible for a considerable burden on the economy. In the USA, medical, pharmaceutical and hospitalisation costs along with the cost of loss of productivity is estimated to be about 12 billion dollars annually. Debility and malaise that follow the acute illness further aggravate the loss of productivity. (Martin and Schoub 1997.)

Many people, including medical and nursing staff trivialise the impact of influenza despite morbidity and mortality statistics in both epidemic and non-epidemic years (Wiselka 1994).

## 2.2 DEFINITION OF INFLUENZA

Influenza is an acute respiratory illness that results from infection with influenza viruses. The viruses mainly affect the upper respiratory tract, nose and throat, and is often accompanied by systemic symptoms such as fever, headache, myalgia and weakness. (Fry 1983:58.)

The clinical features of influenza are often indistinguishable from those caused by other respiratory viruses that may be circulating in the comunity at the same time. Diagnoses of influenza is usually confirmed by isolation of virus or from blood results. (Monto 1995.)

## 2.3 THE INFLUENZA VIRUSES

The viruses were discovered in 1933. They are members of the Orthomyxoviridae family and are recognised as influenza A, B and C (Fry 1983:58). Designation of influenza viruses as types A, B or C if based on antigenic characteristics of the nucleoprotein and matrix protein antigens (Wilson et al. 1991:695).

Influenza A is the most malignant type, responsible for all major epidemics and pandemics. Influenza B can cause less severe but locally widespread epidemics while influenza C has caused only minor epidemics in closed communities. (Fry 1983:59.)

Influenza viruses A, B and C are morphologically similar. The virions are irregularly

shaped spherical particles, 80-120nm in diameter. They consist of a lipid envelope, from whose surface, hemagglutinin and neuraminidase glycoproteins, project. The virus binds to cell receptors via the hemagglutinin, while the neuraminidase degrades the receptor and probably plays a role on the release of virus from infected cells after replication has taken place. The inner surface of the lipid envelope contains the matrix proteins which may be involved in stabilisation of the lipid envelope and virus assembly. The nucleoprotein, with which the genome of the virus is associated, is also contained in the virion along with three polymerase proteins which are essential for transcription and synthesis of viral RNA. The genome of influenza A virus consists of eight single-stranded segments of viral RNA which code for structural and non-structural proteins. The segmented genome allows for frequent reassortment of genes. (Wilson et al. 1991:695.)

Influenza A, B and C viruses are designated according to the site of origin, isolate number and year of isolation. Influenza A viruses are further subtyped on the basis of the surface hemagglutinin and neuraminidase antigens. In human infections, three major subtypes of hemagglutinins (H1, H2 and H3) and two neuraminidases (N1 and N2) have been recognised. The hemagglutinin and neuraminidase antigens in the influenza B and C viruses do not receive subtype designation since intratypic variations in hemagglutinin and neuraminidase antigens are less extensive.(Wilson et al. 1991:695.)

## 2.4 EPIDEMIOLOGY

Influenza outbreaks occur annually, but the extent and severity vary. Global epidemics or pandemics occur approximately every ten to fifteen years. (Wilson et al. 1991:696.)

Pandemics are caused by antigenic shift of influenza A resulting in the appearance if an influenza virus with a novel hemagglutinin or neuraminidase antigen subtype (Wiselka 1994). These antigenic shifts are most likely to occur from the reassortment of genome segments of the influenza A viruses which is why influenza A viruses are responsible for the most severe and most extensive outbreaks (Wilson et al. 1991:696).

Influenza pandemics usually arise in China and spread westward to the rest of Asia, Europe and America. Influenza viruses have been isolated from many different animal species and recent evidence suggests that antigenic shift results from genetic reassortment of viruses between animal and human reservoir. Farming practices in south east Asia, facilitate this process due to the close proximity between humans, ducks and domestic pigs. (Wiselka 1994.)

Between pandemic periods, outbreaks of influenza A or B infection are reported every winter. Antigenic drifts may be responsible for these outbreaks. (Wiselka 1994.) Antigenic drift describes a process of minor antigenic changes resulting from random point mutations (Wilson et al. 1991:696). New strains of influenza A and B are constantly being generated by antigenic drift. Epidemics arise if circulating strains differ

from previous strains encountered by the population. (Wiselka 1994.)

Influenza A epidemics begin suddenly, reach a peak over a 2-3 week period, last for 2-3 months and subsides almost as quickly as it began. Children are usually the first to be affected, presenting with febrile respiratory illnesses. Adults follow with influenza-like illnesses. Rises in industrial and school absenteeism occurs during this time. Increases in hospital admissions for patients with pneumonia, worsening of chronic heart failure and exacerbations of chronic pulmonary diseases also occur during this time. An increase in the number if deaths caused by pneumonia and influenza is a late observation in the outbreak. (Wilson et al. 1991:696.)

Influenza B outbreaks are less extensive and associated with less severe disease than those caused by influenza A virus. Influenza C is usually not associated with human disease, although infection with influenza C is widespread. (Fry 1983:59.)

### 2.4.1 Winter 1998

According to Dr Vardas at the National Institute for Virology in Johannesburg, the circulating strain of virus during May to August 1998 in the Pretoria, Johannesburg region was the Influenza A /Sydney/ 5/97 (H3N2). (Telephone conversation, 11 August 1998.) She also reported that during this period, the children that were affected were of a younger age than normally expected.

McAnerney et al. (1998), reported that the 1998 influenza outbreak in South Africa, started earlier than those of previous years. The first viral isolates were made in week 16 as compared to week 23 of the previous 14 years. An increase morbidity and mortality was noted during this season and had been associated with a strain that is antigenically different from previous strains thus causing more severe disease. It was also noted that the 1998 outbreak occurred in an unusually mild winter season, where as influenza is usually associated with cold weather.

## 2.5 PATHOGENESIS

The viruses are spread by respiratory secretions from infected individuals via aerosols generated by coughs, sneezes and occasionally hand-to-hand contact. The virus invades respiratory tract cells, replicates within 4-6 hours, after which the viruses are released to infect adjacent cells. The cells become necrotic and desquamate. Within several hours most of the respiratory cells are infected. The severity of the illness corresponds with the quantity of virus shed in secretions. The influenza virus is rarely detected in extrapulmonary sites or the bloodstream and the pathogenesis of systemic symptoms such as fever, headaches and myalgia is unknown.(Wilson et al. 1991: 697.)

## 2.6 MANIFESTATIONS

### 2.6.1 Symptoms

Typical influenza illness is characterised by abrupt onset of systemic symptoms such

as headache, feverishness, chilliness, myalgia or malaise accompanied by coughing and sore throat (Arden et.al 1996).

Clinical presentation of influenza can vary, ranging from mild, afebrile respiratory illnesses similar to the common cold to illnesses in which there may be severe prostration with relatively few respiratory symptoms. Patients complain of a feverish sensation and chilliness. Headaches are frontal or generalised. Myalgia usually involve the legs and lumbosacral area, although any part of the body can be affected. Respiratory complaints become more noticeable once the systemic symptoms subside. Patients may even complain of burning in the eyes, photophobia and pain on motion of the eyes. Symptoms of weakness or lassitude (post viral influenzal asthenia) may persist for several weeks after acute illness resolves. (Wilson et al. 1991:698.)

### 2.6.2 Physical Findings

Patient appears flushed. Fever is usually present in the first 24 hours, ranging from 38°C to 41°C. The fever gradually subsides over the next 2-3 days. Pharyngeal examination is usually unremarkable despite a severe sore throat, but mucous membranes may appear hyperaemic and a post nasal drip may be present. Mild cervical lymphadenopathy may be noted. Nasal obstruction of discharge can be present. Chest examination is usually negative in uncomplicated influenza. (Berkow et al. 1992:193.)

## 2.7 COMPLICATIONS

### 2.7.1 Respiratory complications

These are encountered most often.

- influenza viral pneumonia
- secondary bacterial pneumonia, particularly Staphylococcus aureus
- exacerbation of chronic respiratory diseases
- croup and bronchiolitis in infants and young children

### 2.7.2 Non-respiratory complications

- febrile convulsions
- toxic shock syndrome
- Reye's syndrome
- myositis and myoglobinuria
- myocarditis
- neurological sequelae including Guillain-Barrè syndrome, transverse myelitis and encephalitis
- subsequent meningococcal infection
- possible increased incidence of schizophrenia if exposure is in utero during second trimester. (Wiselka 1994.)

## 2.8 DIAGNOSIS

Diagnosis of influenza is easy during epidemics (Hope et al. 1994:206). The diagnosis is usually confirmed by isolation of virus or from serological results (Wiselka 1994). On clinical grounds alone, an individual case of influenza may be difficult to differentiate from an acute respiratory illness caused by other viruses or bacteria. Influenza outbreaks usually occur during winter months and this may be helpful in making a clinical diagnosis. (Wilson et al. 1991:699.)

## 2.9 MANAGEMENT OF INFLUENZA

In an effort to reduce the impact of influenza, two measures are currently being used:

1) Vaccination using inactivated virus
2) Prophylaxis or therapy using antiviral drugs.

### 2.9.1 Influenza vaccines

The use of killed influenza vaccine was first mentioned by Salk in 1945, (cited by Wilselka 1994). The early vaccines contained intact, formalin inactivated viruses. These vaccines were associated with many adverse effects. Two forms of vaccine are available today. Both contain viral particles and not whole viruses. One contains disrupted virus particles that have been partially purified; the other contains only viral surface antigens, namely hemagglutinin and neuraminidase antigens. (Wiselka 1994.)

Each year a new vaccine is formulated. It contains three virus strains, usually 2 type A

and one type B; representing the influenza viruses that are likely to circulate in the upcoming winter. The vaccine is made from viruses that are grown in egg or allantoic fluid. (Arden et al. 1996.) The vaccine used in South Africa for the 1998 winter was a trivalent composed of the following strains: A/Beiging; A/Sydney and B/Beiging or B/Harbin (Vardes, telephone communication, 11 August 1998).

#### 2.9.1.1 Problems with vaccines

Influenza vaccination is strongly recommended for people of all ages, but especially for elderly people living in nursing homes, who are at increased risk of developing influenza related complications or exacerbations of their underlying disease. However a summary of seventeen trials of influenza vaccine in nursing homes, found that the mean efficacy against clinical influenza A and B infection was only 27% and 21% respectively. (Wiselka 1994.) In a study carried out by Libow et al. (1996) at a nursing home, the influenza vaccine was found to have no effect on the incidence of influenza-like illness, length of illness or the associated death rate.

The effectiveness of influenza vaccine depends on the similarity between the virus strains included in the vaccine and those that circulate during the influenza season. If the match between the vaccine and the circulating virus is good, the influenza vaccine is shown to be 70% effective in healthy persons under 65 years of age. But amongst the frail and elderly, efficacy ranges between 30% to 40%. Efficacy decreases if the match is not good. (Arden et al. 1996.)

The vaccine has also been associated with numerous side effects such as: local erythema and tenderness at the site of injection. Low grade fever, myalgia and headache have been reported in the first 24 hours after vaccinations. Allergic reactions, ranging form hives to systemic anaphylaxis, have also occurred due to hypersensitivity to vaccine components; especially egg protein, in which the virus is grown. Anecdotal cases of asthma attacks have been reported after vaccination. In 1976, an increased frequency of Guillain-Barrè syndrome was associated with the Swine influenza vaccine. (Nichol et al. 1996.)

### 2.9.2 Antivirals

Two antiviral agents are commonly used for influenza A infections. Amantadine hydrochloride and rimantadine hydrochloride interfere with the replication cycle of type A, but not type B influenza viruses. (Arden et al. 1996.) Recent studies have been conducted using zanamivir, which has been shown to be effective against influenza A and B viruses (Hayden et al. 1997).

#### 2.9.2.1 Amatadine and rimantadine

Amantadine and its analogue, rimantadine, have a tricyclic chemical structure with an amine side chain and a cage-like configuration. They are believed to act by inhibiting virus uncoating. (Wiselka 1994.) These drugs have been approved for prophylactic and therapeutic use against influenza A (Monto and Arden 1992).

When administered prophylactically to healthy adults or children, before and throughout the epidemic period, both drugs are 70% to 90% effective (Arden et al. 1996). Amantadine has been approved for prophylactic and therapeutic use against influenza A (Monto and Arden 1992). If amantadine is used as treatment within 48 hours of the onset of symptoms, a reduction in virus shedding and a shortening of the duration and severity of symptoms, by a third, have been noted (Wiselka 1994). Rimantadine is currently approved only for prophylaxis in children, but not for treatment in this group (Arden et al. 1996).

2.9.2.1 a) Adverse effects

Both amantadine and rimantadine can cause central nervous system and gastrointestinal side effects in young healthy adults. The side effects caused by amantadine are more severe because amantadine is excreted unchanged, where as rimantadine is metabolised by the liver. The unchanged amantadine and the rimantadine metabolites are excreted by the kidneys. Amantadine accumulates in the blood, especially in individuals with renal impairment, resulting in a high plasma drug concentration which has been associated with serious side effects such as behavioural changes, delirium, hallucinations, agitation and seizures. (Arden et al. 1996.) Less severe side effects include headache, light headedness, dizziness, difficulty concentrating, insomnia, nausea and anorexia (Wiselka 1994).

Amantadine is prescribed with caution in patients with cardiovascular, cerebral or renal

disorders. Unfortunately, these groups of patients are the ones who are at particular risk of developing complications. (Wiselka 1994.)

2.9.2.1 b) Resistance

Influenza A viruses that are resistant to both amantadine and rimantadine have been isolated from as early as 1965. These viruses were detected only where there had been previous exposure to rimantadine or amantadine, for example in nursing homes, where the antivirals are used for prophylaxis. In other words, influenza A viruses that are resistant to the antivirals, do not occur naturally. (Monto and Arden 1992.)

However, in a study conducted in 1992, resistant viruses were isolated which had, had no previous exposure to either rimantadine of amantadine. In other words, They detected resistant viruses that occurred naturally. (Houck et al. 1995.)

### 2.9.2.2 Zanamivir

This is a new antiviral which has been found to be effective against influenza A and B. This drug blocks the action of enzymes which are essential for replication of the infected cell. The drug is however, still being tested and although it is regarded as being safe, upper respiratory, gastrointestinal and intranasal side effects have been reported. (Hayden et al. 1997.)

## 2.10 HOMOEOPATHY AND INFLUENZA

Homoeopathy is an exceptionally safe form of medicine that treats the whole individual. It relies on the body's own powers of self-regulation and self healing. Since its development, nearly two hundred years ago, it has benefited millions of people, all over the world. (Lockie and Geddes 1992:15.)

Whether a condition is caused by a virus, a bacteria or a parasite, is not of prime importance to a homoeopath. It is the symptoms the patient presents with that concern the homoeopath and based on these symptom, a remedy is chosen. Homoeopathic treatment works by stimulating the body's immune system, so that the causative organism is destroyed by the body rather than by medication such as antivirals and antibiotics. (Jouanny 1993:14.)

Orthodox medical treatment has very little to offer when it concerns viral infections. In such illnesses, healing and recovery is dependent upon the healing resources of the body. While the search continues to find antiviral preparations which are free from side-effects, homoeopathy can be used effectively to treat patients in four ways:

- prophylaxis - to generate resistance to the infection
- treatment - to reduce the length and severity of the illness
- restoration - to revitalise the patient during convalescence
- correction of chronic sequelae - to restore the patient to his former state of health. (Savage 1984.)

### 2.10.1 Simillimum and complexes

Simillimum is the name given to the medicine or remedy that best corresponds to the patient's symptoms. Most homoeopathic prescriptions are based on the simillimum principle. In other words, there are no medicines for specific conditions or diseases. Therefore when two patients, suffering from the same condition, consult a homoeopath, they receive different prescriptions, depending on the symptoms they present with. (Vithoulkas 1986:92.)

Complexes are a combination of medicines known to be effective in the treatment of a specific disease. Here the emphasis is placed on the disease and not the symptoms of the patient. This form of treatment has been found to be useful in acute diseases when symptoms are vague. Complex prescribing is gaining popularity among large sections of the medical profession and amoung the public who can buy them over-the-counter. (Ferley 1989.)

### 2.10.2 The epidemic remedy

A remedy that covers a large majority of cases during an epidemic is known as the epidemic remedy. To find it, one lists the prominent symptoms of a series of cases and finds the remedy that most closely fits this composite symptom picture. The epidemic remedy may differ in different localities and may change as time goes on. (Ross 1997.) It was noted by the researcher and other homoeopaths in the Johannesburg and

Pretoria area that Bryonia alba, Allium cepa, Hepar sulphuris and Sulphur were the remedies that covered the influenza symptoms of the 1998 influenza season.

## 2.10.3 The AGEF complex

This complex has been formulated in the thirtieth centicimal potency and successfully used to treat influenza-like syndrome by Dr Ruth Bloch and Dr Barbara Lewis of Cape Town. It consists of Arsenicum Iodatum, Gelsemium sempervirens, Eupatorium perfoliatum and Ferrum phosphoricum.

### 2.10.3.1 Arsenicum iodatum

Also known as iodide of arsenic. Formula: $A_8I_3$. It is found in orange coloured crystals and is soluble in water and alcohol. According to Clark (cited by Matur 1972:142), it is a remedy of wide range and great power. It is indicated for influenza with catarrhal symptoms of eye, ear, nose and throat; for otitis with foetid, corrosive discharge, deafness due to hypertrophied conditions of Eustachian tubes. It is also used in conditions of hay fever with thick yellow discharge alternating with a thin watery discharge, both of which are acrid and excoriating (Matur 1972:142.)

### 2.10.3.2 Gelsemium sempervirens

This is a climbing plant with yellow flowers having a beautiful odour and is commonly known as yellow jasmine. It belongs to the natural order of Loganiaceae. This plant is mostly found in upper India, Europe and U.S.A. (Matur 1972:457.) It is often used for

influenza, where there is an associated muscle weakness with an overpowering aching, tiredness, heaviness, and soreness felt especially in the muscles of the extremities. The patient also complains of dizziness, drowsiness, dullness and shivering. (Vermeulen 1994:448.)

### 2.10.3.3 Eupatorium perfoliatum

The common names for this plant are boneset or thoroughwort. This is a perennial herb with white flowers and the leaves growing at right angles to those immediately above or below. It belongs to the natural order of Compositae and grows wildly in Canada and U.S.A. (Matur 1972:436.) This remedy is indicated in febrile diseases with violent, aching, bone-breaking pains along with restlessness where the patient is unable to keep still in an effort to relieve the pain (Vermeulen 1994:418).

### 2.10.3.4 Ferrum phosphoricum

This is a chemical compound of iron and phosphoric acid. Formula: $Fe_3(PO)_2$ - phosphate of iron. It is indicated for the first stage of all inflammatory affections. (Matur 1972:449.) Patient has a low fever and a tendency towards localised congestion or haemorrhage (Jouanny 1984:152). Useful in the early stages of febrile conditions where there are no specific symptoms (Vermeulen 1994:434).

## 2.11 SUMMARY

Outbreaks of influenza has plagued Man for centuries. As yet no safe, effective

allopathic treatment has been discovered to help control this condition. Homoeopathy, however, has been shown to be effective in treating patients suffering from influenza like syndromes, rapidly and gently. Simillimum is usually the most effective homoeopathic treatment to give to a patient, but often the symptoms in an acute condition are too vague to prescribe only one remedy. The aim of this study was to find a combination of remedies that can be used by anyone and produce positive results despite not having used the simillimum.

# CHAPTER THREE

# MATERIALS AND METHODS

## 3.1 STUDY DESIGN

The aim of the study was to evaluate the efficacy of the homoeopathic complex consisting of Arsenicum iodatum, Gelsemium sempervirens, Eupertorium perfoliatum and Ferrum phosphoricum in the treatment of influenza type syndrome in terms of the patient's temperature and the patient's response to the treatment. The complex was prepared by Pharma Natura.

The trial was a placebo-controlled, double-blind study. Enrollment in the study was planned for 30 patients, for a duration of five days. The study was conducted in Johannesburg and Pretoria, over a period of five months, from April to August 1998.

## 3.2 SUBJECTS

Advertisements requesting participation in a clinical trial involving homoeopathic treatment of influenza type syndrome, were placed on notice boards at supermarkets as well as in local newspapers.

Thirty patients were obtained by convenience sampling. The following criteria were used to determine eligible patients:

- the patient was between the age of 18 and 60 years;
- the patient had an oral temperature of 37.8°C or greater than 37.8°C (Berkow and Fletcher 1992:8);
- the patient had to suffer from muscle pain, a general feeling of illness and any two of the following symptoms: shivering, headache, coughing, irritation of nasal mucosa or a sore throat;
- the first manifestation of the influenza syndrome occurred less than 24 hours before entry into study;
- the patient had not used any analgesic, antibiotics or anti-influenza medication for the presenting symptoms
- the patient did not suffer from any complications of influenza, for example tracheitis, bronchitis, pneumonia. (Hayden et al. 1997.)

Patients gave written consent after having been informed as to the nature, meaning and extent of the clinical trial. Patients were randomly allocated to either the treatment or the placebo groups. Randomisation of patients occurred as follows. The verum and the placebo were indistinguishable. A neutral member randomly allocated numbers to the fifteen vials of verum and to the fifteen vials of placebo. The patient was asked to choose a number and the corresponding vial was given to the patient. Neither the patient nor the researcher knew whether the patient was given verum or placebo.

## 3.3 INTERVENTIONS

At the start of the trial, participants were introduced to the study. Details of the symptoms the patient was experiencing were taken note of and a physical examination was performed on each patient. The patient's oral temperature was recorded.

The patients were instructed to take the medication sublingually at a two hourly interval, for the next five days. Patients attended follow-up consultations on the third and fifth days during which symptoms were assessed and changes were noted.

## 3.4 MEASUREMENTS AND OTHER OBSERVATIONS

Participants were requested to rate their symptoms on days 1, 3 and 5. This was achieved by using an adapted questionnaire used by Porter (1995). The questionnaire was subdivided into four components: i) systemic affections; ii) respiratory affections; iii) physical findings; iv) temperature (See Appendix A).

Severity was rated on a four point scale in which a score of 0 indicated no symptoms; a score of 1 indicated mild symptoms; a score of 2 indicated moderate symptoms and a score of 3 indicated severe symptoms.

Patients were also requested to take their oral temperature, morning and evenings, during the five day duration of the trial. The patient's ability to take their temperatures was assessed at the first consultation by comparing their readings to that of the

researcher.

Physical findings, using the four point scale mentioned above, were rated and recorded by the researcher on days 1, 3 and 5.

## 3.5 STATISTICAL ANALYSIS

The sample size per group is small (15<30), in which case non-parametric tests were used for statistical data analysis. The ratings given for the different symptoms under systemic affection, respiratory affections and physical findings respectively, were added for each of the three consultations. Temperatures recorded by the researcher were used. An average of the morning and evening temperatures recorded by the patients over the five day trial period were used.

**Procedure 1:**

**Comparison between groups 1 and 2**

The Mann-Whitney unpaired two-tailed test was used to compare groups 1 (placebo) and 2 (treatment) with respect to each variable of interest. The two groups were treated as being independent of one another (unpaired). The purpose was to find out whether there was any significant difference between the two groups at the $\alpha = 0.05$ level of significance.

**Hypothesis testing and decision rule:**

The null hypothesis $H_0$ states that there is no significant difference between the placebo and the treatment group with respect to the variable of interest. The alternative hypothesis $H_1$ states that there is a significant difference between the two groups.

$H_0$: $\mu_1 = \mu_2$

$H_1$: $\mu_1$ and $\mu_2$ are significantly different from each other

$\alpha = 0.05$ = level of significance of test.

**Decision rule:**

Reject $H_0$ if $P \leq \alpha/2$

Accept $H_0$ if $P > \alpha/2$

P is the observed Probability value which is equal to half of the two-tailed Z-value. That is P = (two-tailed Z-value)/2 (van den Honert 1997:213-237)

**Procedure 2:**

Wilcoxon's signed rank test was used within group 1 (placebo) to find out whether there is any significant improvement between consultations 1 and 2, 1 and 3, and 2 and 3. All tests were done at the $\alpha = 0.05$ level.

**Hypothesis testing and decision rule:**

The null hypothesis $H_0$ states that there is no significant improvement between consultations 1 and 2, 1 and 3, and 2 and 3 within the placebo group with respect to the variable of interest. The alternative hypothesis $H_1$ states the contrary of what the null hypothesis does.

$H_0$: There is no significant improvement

$H_1$: There is a significant improvement

$\alpha = 0.05$ =level of significance of test.

**Decision rule:**

Reject $H_0$ if $P \leq \alpha/2$

Accept $H_0$ if $P > \alpha/2$

P is the observed Probability value which is equal to half of the two-tailed Z-value. That is P = (two-tailed Z-value)/2 (van den Honert 1997:213-237)

**Procedure 3:**

Wilcoxon's signed rank test was used within group 2 (treatment) to find out whether there is any significant improvement between consultations 1 and 2, 1 and 3, and 2 and 3. All tests were done at the $\alpha = 0.05$ level.

**Hypothesis testing and decision rule:**

The null hypothesis $H_0$ states that there is no significant improvement between consultations 1 and 2, 1 and 3, and 2 and 3 within the treatment group with respect to the variable of interest. The alternative hypothesis $H_1$ states the contrary of what the null hypothesis does.

$H_0$: There is no significant improvement

$H_1$: There is a significant improvement

$\alpha = 0.05$ =level of significance of test.

**Decision rule:**

Reject $H_0$ if $P \leq \alpha/2$

Accept $H_0$ if $P > \alpha/2$

P is the observed Probability value which is equal to half of the two-tailed Z-value. That is P = (two-tailed Z-value)/2 (van den Honert 1997:213-237)

**Procedure 4:**

Summary statistics (mean, mode, median, standard error, the coefficient of variation) were obtained.

Statistical package

The statistical package STATSGRAPHICS version 6 + was used for data entry and analysis.

# CHAPTER FOUR

# RESULTS

## 4.1 CRITERIA FOR ADMISSIBILITY OF THE DATA

Only data obtained from questionnaires and temperature charts completed by patients and the researcher were used.

## 4.2 SPECIFIC TREATMENT OF THE DATA

The questionnaire was divided into four sections comprising of systemic affections, respiratory affections physical findings and temperature. (See Appendix A.) Scores given for each of the symptoms and signs in the first three sections were added to give a total score for each section. These totals along with the temperatures for each consultation were transferred to a spread sheet. (See Appendix C.) The figures obtained were entered into the staristical package Statsgraphics version 6+ to obtain P-values.

An average of the daily temperatures recorded by the patients were transferred to a spread sheet. (See Addendix D.) These temperatures were entered into the statistical package and P-values were obtained.

## 4.3 SYSTEMIC AFFECTIONS

Table 4.3.1 Difference in systemic affections between placebo and treatment groups.

| Consultation | Median values (placebo) | Median values (treatment) | P-value | α/2 | Decision made |
|---|---|---|---|---|---|
| 1 | 11 | 9 | 0.23 | 0.025 | accept $H_o$ |
| 2 | 5 | 6 | 0.93 | 0.025 | accept $H_o$ |
| 3 | 4 | 1 | 0.07 | 0.025 | accept $H_o$ |

(Mann-Whitney unpaired two-tailed test)

($H_o$ = null hypothesis)

Results from table 4.3.1 show that there was no significant difference in improvement of systemic affections between the placebo and the treatment group.

Table 4.3.2 Improvement of systemic affections within the placebo group.

| Consultation | P-value | α/2 | Decision made |
|---|---|---|---|
| 1 and 2 | 0.003 | 0.025 | reject $H_o$ |
| 2 and 3 | 0.043 | 0.025 | accept $H_o$ |
| 1 and 3 | 0.002 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.3.2 show that there was a significant improvement of systemic affections between the first and second, and first and third consultations, within the placebo group.

Table 4.3.3 Improvement of systemic affections within the treatment group.

| Consultation | P-value | $\alpha/2$ | Decision made |
|---|---|---|---|
| 1 and 2 | 0.039 | 0.025 | accept $H_o$ |
| 2 and 3 | 0.0005 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.0003 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results form Table 4.3.3 show that there was a significant improvement of systemic affections between the first and third, and second and third consultations, within the treatment group.

## 4.4 RESPIRATORY AFFECTIONS

Table 4.4.1 Difference in respiratory affections between placebo and treatment groups.

| Consulta-tion | Median value (placebo) | Median value (treatment) | P-value | α/2 | Decision made |
|---|---|---|---|---|---|
| 1 | 11 | 9 | 0.112 | 0.025 | accept $H_o$ |
| 2 | 9 | 6 | 0.022 | 0.025 | reject $H_o$ |
| 3 | 5 | 5 | 0.142 | 0.025 | accept $H_o$ |

(Mann-Whitney unpaired two-tailed test)

($H_o$ = null hypothesis)

Results from Table 4.4.1 shows that there was a significant difference in the improvement of respiratory affections between placebo and treatment groups at the second consultation.

Table 4.4.2 Improvement of respiratory affections within the placebo group.

| Consultation | P-value | α/2 | Decision made |
|---|---|---|---|
| 1 and 2 | 0.57 | 0.025 | accept $H_o$ |
| 2 and 3 | 0.002 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.016 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.4.2 show that there was a significant improvement of respiratory affections between the first and third, and the second and third consultations within the placebo group.

Table 4.4.3 Improvement of respiratory affections within the treatment group.

| Consultation | P-value | $\alpha/2$ | Decision made |
|---|---|---|---|
| 1 and 2 | 0.027 | 0.025 | accept $H_o$ |
| 2 and 3 | 0.016 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.0005 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.4.3 show that there was a significant improvement of respiratory affections between the first and third, and the second and third consultation within the treatment group.

## 4.5 PHYSICAL FINDINGS

Table 4.5.1 Difference in physical findings between placebo and treatment groups.

| Consultation | Median value (placebo) | Median value (treatment) | P-value | α/2 | Decision made |
|---|---|---|---|---|---|
| 1 | 8 | 7 | 0.147 | 0.025 | accept $H_o$ |
| 2 | 6 | 5 | 0.208 | 0.025 | accept $H_o$ |
| 3 | 2 | 2 | 0.408 | 0.025 | accept $H_o$ |

(Mann-Whitney unpaired two-tailed test)

($H_o$ = null hypothesis)

Results from Table 4.5.1 shows that there was no significant difference in the improvement of physical findings between placebo and treatment groups.

Table 4.5.2 Improvement of physical findings within the placebo group.

| Consultation | P-value | α/2 | Decision made |
|---|---|---|---|
| 1 and 2 | 0.0003 | 0.025 | reject $H_o$ |
| 2 and 3 | 0.016 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.002 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.5.2 show that there was a significant improvement of physical findings between the first and second, second and third, and first and third consultations within the placebo group.

Table 4.5.3 Improvement of physical findings within the treatment group.

| Consultation | P-value | $\alpha/2$ | Decision made |
|---|---|---|---|
| 1 and 2 | 0.039 | 0.025 | accept $H_o$ |
| 2 and 3 | 0.003 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.001 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.5.3 show that there was a significant improvement of physical findings between the first and third, and the second and third consultations within the treatment group.

## 4.6 TEMPERATURES RECORDED BY THE RESEARCHER

Table 4.6.1 Difference in temperatures between placebo and treatment groups, recorded by the researcher.

| Consulta-tion | Median value (placebo) | Median value (treatment) | P-value | α/2 | Decision made |
|---|---|---|---|---|---|
| 1 | 38.4°C | 38.4°C | 0.69 | 0.025 | accept $H_o$ |
| 2 | 37°C | 36.9°C | 0.818 | 0.025 | accept $H_o$ |
| 3 | 36.6°C | 36.7°C | 0.867 | 0.025 | accept $H_o$ |

(Mann-Whitney unpaired two-tailed test)

($H_o$ = null hypothesis)

Results from Table 4.6.1 shows that there was no significant difference in the temperatures between placebo and treatment groups.

Table 4.6.2 Improvement of temperatures recorded by researcher within the placebo group.

| Consultation | P-value | α/2 | Decision made |
|---|---|---|---|
| 1 and 2 | 0.0003 | 0.025 | reject $H_o$ |
| 2 and 3 | 0.009 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.0003 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.6.2 show that there was a significant improvement of temperatures between the first and second, second and third, and first and third consultations within the placebo group.

Table 4.6.3 Improvement of temperatures recorded by researcher within the treatment group.

| Consultation | P-value | $\alpha/2$ | Decision made |
|---|---|---|---|
| 1 and 2 | 0.002 | 0.025 | reject $H_o$ |
| 2 and 3 | 0.0008 | 0.025 | reject $H_o$ |
| 1 and 3 | 0.0003 | 0.025 | reject $H_o$ |

(Wilcoxon signed rank test)

($H_o$ = null hypothesis)

Results from Table 4.6.3 show that there was a significant improvement of temperatures between the first and second, second and third, and first and third consultations within the treatment group.

## 4.7 TEMPERATURES RECORDED BY PATIENTS

Table 4.7.1 Difference in temperatures between placebo and treatment groups, recorded by the patients.

| Day | Median value (placebo) | Median value (treatment) | P-value | $\alpha/2$ | Decision made |
|---|---|---|---|---|---|
| 1 | 38.3°C | 38.4°C | 0.66 | 0.025 | accept $H_o$ |
| 2 | 37.7°C | 37.5°C | 0.49 | 0.025 | accept $H_o$ |
| 3 | 37.1°C | 36.8°C | 0.38 | 0.025 | accept $H_o$ |
| 4 | 36.7°C | 36.8°C | 0.60 | 0.025 | accept $H_o$ |
| 5 | 36.5°C | 36.5°C | 0.43 | 0.025 | accept $H_o$ |

($H_o$ = null hypothesis)

Results from Table 4.7.1 shows that there was no significant difference in improvement of temperatures between the placebo and treatment groups.

# CHAPTER FIVE

# DISCUSSION

## 5.1 INTERPRETATION

The results of this study show that there was an overall improvement in patients suffering from influenza type syndrome in both the placebo and treatment group in terms of patient response and temperature.

Patient response was divided into systemic affections and respiratory affections. Improvement of systemic affections occurred in both placebo and treatment groups. (See Tables 4.3.2 and 4.3.3) The degree of improvement was the same for both groups. (See Table 4.3.1)

A significant difference was noted at the second consultation with regard to respiratory affections, where the treatment group showed a better response. (See Table 4.4.1) The severity of respiratory symptoms in the treatment group was less than those of the placebo group at the first consultation, which may explain the difference in improvement between the two groups. On the third consultation, however, the improvement was the same for both groups.

The resolution of physical signs in the treatment group occurred at about the same rate

as that of the placebo group. (See Tables 4.5.1, 4.5.2 and 4.5.3)

The improvement noted in both groups can be explained by the fact that in uncomplicated cases of influenza, the acute illness generally resolves over a two to five day period and most patients recover within one week (Berkow and Fletcher 1992:193).

In terms of temperatures recorded by both the researcher and the patient, most temperatures had dropped below 37.8°C by day 3 in both the placebo and treatment groups. (See Figures 4.6.1 and 4.7.1 and Appendix C and D.) At the second consultation (Day 3), two patients in the placebo group and two patients in the treatment group were noted to have temperatures ≥ 37.8°C, by the researcher. The two temperatures of the treatment group (38.3°C and 39.9°C) were much higher than those of the placebo group (37.8°C and 37.8°C). This may merely be coincidental but may also demonstrate the initial aggravation of symptoms that occurs after the correct remedy has been administered (Vithoulkas 1986:228). Further investigation is needed in order to attain an explanation for this observation.

The return of most patient's body temperature to normal, within three days, can be explained by the fact that the temperature rises rapidly within the first 24 hours of influenza infection and is generally followed by a gradual defervescence over a two to three day period (Wilson et al. 1991:698).

It was hypothesised that the chosen homoeopathic complex would bring about a rapid improvement in the treatment of influenza type syndrome in the treatment group as compared to the placebo group in terms of: 1) the patient's response to the treatment and 2) the patient's temperature. The study does not support these hypotheses. The complex is therefore not effective in the treatment of influenza type syndrome.

## 5.2 ARGUMENT

This study confirms the basic principle of homoeopathy, that is, like cures like. The remedy prescribed to a patient must correspond to the **symptoms** the patient presents with and not the condition the patient is suffering from. Homoeopathic medicines are most effective when prescribed on the individualising symptoms of the patient (Vithoulkas 1986:91). When medicines are prescribed according to the condition, the results can be disappointing.

When the similarity, or 'homoeopathicity' of the remedy is a close one, it is found that the headache, fever and distress associated with influenza, soon subside and that most cases go on to a rapid recovery without grave complications (Ross 1997).

## 5.3 SPECULATIONS

During the trial, it was noted by the researcher, that the symptoms presented by most of the patients did not correspond with the remedies in the complex tested . Instead remedies such as Bryonia alba, Hepar sulphuris, Allium cepa and Sulphur were

indicated. The results may have been different if these remedies were used in the complex.

The fact that the 1998 influenza strain was different in two ways may also explain why this complex which had previously been successful in treating influenza type syndrome may not have worked for the 1998 influenza outbreak. The 1998 strain was i)antigenically different from previous years and ii) isolates were made in week 16 instead of week 23 as was the case for the previous 14 years. As a result different remedies were needed to treat the 1998 outbreak.

The researcher has found that in acute conditions like influenza, higher potencies such as 200CH and 1M work better. The potency used in this trial was a 30CH, which may not have been effective in bringing about rapid results.

Attention should have been paid to individual symptoms of the questionnaire instead of grouping into the different sections. This would have allowed for a better understanding of the action of the complex. Improvements in individual symptoms would have been detected easily and possible trends could have been noted.

Case takings were not done to fulfill homoeopathic requirements. Symptoms were noted but details needed for a homoeopathic prescription were neglected. Had these details been noted, the researcher would have been able to repertorise each case and make

note of the indicated remedy. This would have allowed the researcher to determine exactly which remedies should have been used in the complex, to treat the 1998 influenza epidemic.

# CHAPTER SIX

# CONCLUSION AND RECOMMENDATIONS

## 6.1 CONCLUSION

The homoeopathic complex consisting of Arsenicum iodatum, Gelsemium sempervirens, Eupertorium perfoliatum and Ferrum phosphoricum was found to be ineffective in the treatment of influenza type syndrome in terms of patient's response to treatment and the patient's temperature.

The rate of improvement concerning systemic affections, respiratory affections, physical findings and temperature was the same for both the groups, proving that the complex used did not speed up the rate of recovery.

## 6.2 RECOMMENDATIONS

The complex used has been proven to be ineffective, but may have worked in another influenza epidemic. Future studies of homoeopathic complexes for the treatment of influenza like syndromes, should consist of remedies that best correlate with the symptoms of most patients during that particular influenza epidemic. The remedies used in these complexes will vary from year to year and can only be determined in the first few weeks of the influenza epidemic.

Once the complex has been determined for a particular influenza epidemic, its value as a prophylactic medicine could also be assessed and used in the same way the influenza vaccine is used.

Reportorization of symptoms of patients participating in any future studies using homoeopathic influenza complexes may reveal useful information as to remedies that were indicated during the time of that trial.

A comparative study using any influenza complex of a 30CH potency and the same complex of 200CH potency could be conducted, in order to determine whether one potency is more effective than the other.

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# APPENDIX A

NAME:_____

DAY: 1.....3.....5

## QUESTIONNAIRE OF CLINICAL SYMPTOMS AND SIGNS

RATING: Severe----------3
Moderate----------2
Mild----------1
None----------0

**SECTION A:** SYMPTOMS - Rated by the patient

Rate the severity of the following symptoms using the above scale by circling the appropriate response.

1) Systemic Affections

Chills..... 0 1 2 3

Fatigue..... 0 1 2 3

Muscle pain..... 0 1 2 3

Lumbar pain..... 0 1 2 3

Headache..... 0 1 2 3

Nausea..... 0 1 2 3

Vomiting..... 0 1 2 3

2) Respiratory Affections

Sneezing..... 0 1 2 3

Nasal obstruction..... 0 1 2 3

Sore throat..... 0 1 2 3

RATING: Severe----------3
Moderate----------2
Mild----------1
None----------0

Hoarseness..... 0 1 2 3

Cough..... 0 1 2 3

Sputum..... 0 1 2 3

Epistaxis..... 0 1 2 3

**SECTION B:** SIGNS - Rated by researcher

Flushed face..... 0 1 2 3

Conjunctival irritation..... 0 1 2 3

Nasal discharge..... 0 1 2 3

Pharyngeal infection..... 0 1 2 3

Cervical adenopathy..... 0 1 2 3

TEMPERATURE :.....

# APPENDIX B

NAME:_____

## ORAL TEMPERATURE MEASUREMENTS

Instructions to patients concerning measuring procedure:

1. Shake the glass thermometer down to below 35.5 degrees Celsius
2. Insert it under the tongue, and close both lips.
3. Wait 3 to 5 minutes.
4. Then read the thermometer.
5. Re-insert thermometer for a minute and read again. If the temperature is still rising, repeat this procedure until the reading remains stable.

| | MORNING | EVENING |
|---|---|---|
| DAY 1 | | |
| DAY 2 | | |
| DAY 3 | | |
| DAY 4 | | |
| DAY 5 | | |

# APPENDIX C

Results of severity of symptoms from questionnaire.

## SYSTEMIC AFFECTIONS

| | Consultation 1 Placebo (Day 1) | Consultation 1 Treatment (Day 1) | Consultation 2 Placebo (Day 3) | Consultation 2 Treatment (Day 3) | Consultation 3 Placebo (Day 5) | Consultation 3 Treatment (Day 5) |
|---|---|---|---|---|---|---|
| 1 | 11 | 18 | 10 | 8 | 6 | 0 |
| 2 | 12 | 14 | 5 | 1 | 4 | 0 |
| 3 | 10 | 7 | 7 | 4 | 2 | 2 |
| 4 | 14 | 11 | 13 | 6 | 13 | 1 |
| 5 | 11 | 9 | 9 | 6 | 3 | 1 |
| 6 | 11 | 11 | 4 | 10 | 4 | 9 |
| 7 | 10 | 7 | 3 | 9 | 0 | 0 |
| 8 | 8 | 7 | 4 | 3 | 2 | 1 |
| 9 | 15 | 14 | 15 | 12 | 12 | 6 |
| 10 | 12 | 8 | 1 | 10 | 1 | 5 |
| 11 | 6 | 5 | 4 | 2 | 5 | 0 |
| 12 | 6 | 5 | 8 | 6 | 4 | 0 |
| 13 | 12 | 10 | 2 | 5 | 15 | 1 |
| 14 | 14 | 8 | 4 | 4 | 0 | 2 |
| 15 | 14 | 14 | 5 | 1 | 0 | 1 |

## RESPIRATORY AFFECTIONS

| | Consultation 1 Placebo (Day 1) | Consultation 1 Treatment (Day 1) | Consultation 2 Placebo (Day 3) | Consultation 2 Treatment (Day 3) | Consultation 3 Placebo (Day 5) | Consultation 3 Treatment (Day 5) |
|---|---|---|---|---|---|---|
| 1 | 10 | 10 | 12 | 6 | 8 | 1 |
| 2 | 13 | 1 | 10 | 0 | 5 | 0 |
| 3 | 7 | 7 | 4 | 2 | 5 | 2 |
| 4 | 12 | 11 | 17 | 7 | 12 | 3 |
| 5 | 4 | 7 | 7 | 2 | 2 | 2 |
| 6 | 12 | 11 | 8 | 11 | 3 | 6 |
| 7 | 9 | 12 | 6 | 10 | 1 | 6 |
| 8 | 11 | 10 | 11 | 5 | 4 | 3 |
| 9 | 9 | 8 | 13 | 9 | 11 | 2 |
| 10 | 12 | 9 | 5 | 8 | 2 | 5 |
| 11 | 12 | 7 | 9 | 7 | 8 | 2 |
| 12 | 13 | 2 | 10 | 4 | 6 | 2 |
| 13 | 14 | 11 | 13 | 4 | 10 | 6 |
| 14 | 2 | 5 | 7 | 4 | 5 | 4 |
| 15 | 6 | 10 | 6 | 9 | 0 | 6 |

## PHYSICAL FINDINGS

| | Consultation 1 Placebo (Day 1) | Consultation 1 Treatment (Day 1) | Consultation 2 Placebo (Day 3) | Consultation 2 Treatment (Day 3) | Consultat5ion 3 Place1bo (Day2 5) | Consultation 3 Treatment (Day 5) |
|---|---|---|---|---|---|---|
| 1 | 8 | 13 | 6 | 5 | 2 | 2 |
| 2 | 5 | 8 | 2 | 1 | 2 | 0 |
| 3 | 10 | 4 | 8 | 5 | 1 | 2 |
| 4 | 9 | 9 | 6 | 7 | 5 | 2 |
| 5 | 7 | 5 | 5 | 4 | 2 | 2 |
| 6 | 8 | 6 | 7 | 10 | 5 | 7 |
| 7 | 8 | 10 | 2 | 5 | 1 | 3 |
| 8 | 8 | 7 | 4 | 3 | 1 | 1 |
| 9 | 9 | 5 | 6 | 3 | 7 | 1 |
| 10 | 6 | 7 | 2 | 9 | 1 | 4 |
| 11 | 8 | 8 | 7 | 5 | 6 | 5 |
| 12 | 9 | 5 | 6 | 3 | 3 | 0 |
| 13 | 11 | 8 | 5 | 2 | 13 | 3 |
| 14 | 10 | 7 | 7 | 2 | 1 | 1 |
| 15 | 11 | 11 | 8 | 5 | 3 | 2 |

# TEMPERATURES RECORDED BY RESEARCHER

| | Consultation 1 Placebo (Day 1) | Consultation 1 Treatment (Day 1) | Consultation 2 Placebo (Day 3) | Consultation 2 Treatment (Day 3) | Consultation 3 Placebo (Day 5) | Consultation 3 Treatment (Day 5) |
|---|---|---|---|---|---|---|
| 1 | 38.6 | 38.8 | 37 | 37.5 | 36.6 | 36.8 |
| 2 | 38.4 | 38.4 | 37.3 | 37 | 37 | 36.8 |
| 3 | 38.2 | 38.5 | 37.8 | 36.8 | 36.7 | 36.5 |
| 4 | 37.8 | 38.2 | 36.8 | 36.8 | 36.6 | 36.8 |
| 5 | 38.2 | 37.8 | 37 | 37 | 36.6 | 36.8 |
| 6 | 38.4 | 37.8 | 36.6 | 37.2 | 36.7 | 36.9 |
| 7 | 38.5 | 38.6 | 36.3 | 36.7 | 36.2 | 36.5 |
| 8 | 38 | 38.4 | 37.2 | 36.6 | 37 | 36.4 |
| 9 | 38 | 38.5 | 36.5 | 36.8 | 36.5 | 36.7 |
| 10 | 38.5 | 38.5 | 36.8 | 38.3 | 36.5 | 37.2 |
| 11 | 37.8 | 37.8 | 36.5 | 37.4 | 36.5 | 36.4 |
| 12 | 38.4 | 37.9 | 37.8 | 39.9 | 37.1 | 36.7 |
| 13 | 38.4 | 38.1 | 36.4 | 36.9 | 36.4 | 36.4 |
| 14 | 38.7 | 38.7 | 37.2 | 36.3 | 36.4 | 36.2 |
| 15 | 38.5 | 38.9 | 37.3 | 36.4 | 36.9 | 36.4 |

# APPENDIX D

## TEMPERATURES RECORDED BY PATIENTS

| | Day 1 Placebo | Day 1 Treat-ment | Day 2 Placebo | Day 2 Treat-ment | Day 3 Placebo | Day 3 Treat-ment | Day 4 Placebo | Day 4 Treat-ment | Day 5 Placebo | Day 6 Treat-ment |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 38.7 | 38.8 | 37.7 | 37.1 | 37.1 | 37.7 | 36.8 | 37.1 | 36.6 | 37 |
| 2 | 38.3 | 38.2 | 38.1 | 37.1 | 37.3 | 36.9 | 37.1 | 36.9 | 37 | 37 |
| 3 | 38.2 | 38.5 | 37.7 | 38.7 | 37.7 | 36.7 | 37 | 36.1 | 36.8 | 35.8 |
| 4 | 37.5 | 37.4 | 37 | 37.5 | 37 | 36.7 | 36.5 | 36.9 | 36.3 | 36.7 |
| 5 | 38.2 | 37.8 | 37.8 | 37.9 | 37.3 | 37.4 | 36.9 | 37 | 36.7 | 36.9 |
| 6 | 38.2 | 37.8 | 37.3 | 37.7 | 37.3 | 37.1 | 37 | 36.9 | 36.7 | 37 |
| 7 | 38.5 | 38.7 | 37.8 | 37.1 | 36.9 | 37.1 | 36.5 | 36.8 | 36.5 | 36.4 |
| 8 | 37.8 | 38.4 | 36 | 37.1 | 37 | 36.6 | 37 | 36.5 | 37 | 36.5 |
| 9 | 38 | 38.5 | 36.8 | 37.1 | 36.5 | 36.8 | 36.5 | 36.8 | 36.5 | 36.6 |
| 10 | 38.3 | 37.8 | 36.5 | 39 | 35.7 | 38.1 | 35.6 | 36.7 | 35.5 | 36.8 |
| 11 | 37.8 | 38 | 36.6 | 37.3 | 36.6 | 36.9 | 36.6 | 36.8 | 36.5 | 36.8 |
| 12 | 38.4 | 37.9 | 37.8 | 37.9 | 37.4 | 36.8 | 36.7 | 37.1 | 36.5 | 36.6 |
| 13 | 38.4 | 38.5 | 37.8 | 37.1 | 36.7 | 36.8 | 36.5 | 36.9 | 36.2 | 36.3 |
| 14 | 38.7 | 38.6 | 38.4 | 37 | 37.4 | 36.5 | 36.7 | 36.7 | 36.5 | 36.9 |
| 15 | 38.3 | 38.9 | 37.9 | 38 | 37.3 | 36.5 | 37 | 36.5 | 36.9 | 36.4 |