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Evaluate the Clinical Efficacy of Insty in the Treatment of Pyrexia

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ABSTRACT

To evaluate safety and efficacy of Anti-pyretic granules in patients with upper respiratory tract infection (URTI) with cough, cold, and flu symptoms along with pyrexia.

Introduction: Herbs had been used by all cultures throughout history. Many drugs commonly used today are of herbal origin. The modern day scientific techniques have proven benefits of herbal drugs. The present study was designed to scrutinize the antipyretic activity of Herbion Anti-pyretic granules in patients with upper respiratory tract infection (URTI) including cough, cold, and flu along with mild to moderate fever. **Method:** Randomized open clinical study in 50 patients including Children, Adult Male and Female patients with pyrexia associated with cough, cold or flu. Herbion Anti-pyretic granules were given at a dose of 2-3 sachets/day to 50 patients and response of drug is recorded on the scheduled follow-up after 2days and 5days. **Results:** The overall results shows that out of 50 patients, 39 patients were recovered on day1, 7 patients were recovered on day2 and 4 patients were recovered on day3 at a dose of 2-3 sachets/day.

Conclusion: It was concluded that, the trial drug (Herbion Anti-pyretic granules) were safe, and effective in the treatment of low grade (<102°F) pyrexia associated with upper respiratory tract infection including cough, cold, and flu.

Key Words: Pyrexia, fever, Insty, Herbion Anti-pyretic granules, Sisymbrium irrio, Achillea millefolium, Thea sinensis, Valeriana officinalis, Vitis venefera.

INTRODUCTION

Fever is one of the most common medical signs. It is part of about 30% of healthcare visits by children and occurs in up to 75% of adults who are seriously sick. [1]

The use of herbal medicinal products and supplements

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has increased tremendously over the past three decades with not less than 80% of people worldwide relying on them for some part of primary healthcare [2]

Herbs had been used by all cultures throughout history. Many drugs commonly used today are of herbal origin. The modern day scientific techniques

have proven benefits of herbal drugs. Herbal medicines have been widely utilized as effective remedies for the prevention and treatment of multiple health conditions for centuries by almost every known culture. The first documented records of herbal medicine use date back 5,000 years in China. Similarly, India's Ayurvedic medicine tradition is thought to be more than 5,000 years old and herbal medicines remain an essential component of its practice. Today, the populations of certain countries still depend on herbal medicines to address their healthcare needs. In the U.S. the use of herbal medicines continues to grow since Eisenberg et al. conducted the first national study of complementary and alternative medicine use. [3]

Herbion Anti-pyretic granules is a polyherbal product that is commonly used in the treatment of cough, cold and flu usually accompanied by fever. The present study was designed to scrutinize the antipyretic activity of Anti-pyretic granules in patients with upper respiratory tract infection (URTI) including cough cold and flu along with fever.

METHOD

A Randomized open clinical study was conducted to see the efficacy and safety of Herbion Anti-pyretic granules in patients with low grade fever (<102°F) pyrexia associated with upper respiratory tract infections including cough, cold and flu. Total number of selected patients were 50, including Children, Adult Male and Female patients with pyrexia.

Eligibility:

- Age eligible for study 2 years and above
- Gender eligible for study: Male and female both

Inclusion Criteria:

- Patients with pyrexia
- Patients 2 years of age and above.
- Participant should be the resident of city where he /she enrolled at their respective center.

Exclusion Criteria:

- Hypersensitivity to any of the ingredients of the preparation.
- Patients less than 2 years of age
- Pregnant women.
- Lactating women
- Patients who are taking other anti-pyretic medicines

Table 1: Herbion Anti-pyretic granules comprises of five ingredients.

Ingredient	Quantity(mg)	Common Name	Properties/actions
Sisymbrium irio	165	London rocket/khakasi	Anti-pyretic effect
Achillea millefolium	100	yarrow/Biranjasif	Anti-pyretic and anti-inflammatory
Thea sinensis	100	tea plant/ barg-e-chah	Bronchodilator, Anti-depressant
Valeriana officinalis	100	True valerian/ Baalchar	Sedative
Vitis venifera	50	Raisin/Munakka	cooling,expectorant, demulcent,laxative,sores and anti-inflammatory

PROCEDURE FOR STUDY

After detailed history and examination, those patients fulfilling the inclusion criteria were selected for the trial. A written voluntary informed consent was obtained for the clinical trial, and the drug was given to the patients.

Herbion Anti-pyretic granules was given at a dose of 2-3 sachets/day to 50 patients and response of drug is recorded on the scheduled follow-up after 2 days. Patients were advised to take Herbion Anti-pyretic granules by dissolving each sachet/dose in a glass of hot water or tea.

DISCUSSION

Sisymbrium irio:

Sisymbrium irio, known as London rocket, is a plant in the family Brassicaceae. It is an annual herb exceeding three feet in height with open, slender stem branches. [4]

The seeds of Khaksi (Sisymbrium irio L.) are

attributed with varied medicinal properties in the Unani system of medicine. These are used for the treatment of inflammatory conditions, boils, pimples, cough, cholera and non-specific fevers. ?5? London rocket is used in the Middle East to treat coughs and chest congestion, to relieve rheumatism, to detoxify the liver and spleen, and to reduce swelling and clean wounds. [6]

Achillea millefolium:

Achillea millefolium known commonly as yarrow or common yarrow is a flowering plant in the family Asteraceae. It is native to temperate regions of the Northern Hemisphere in Asia, Europe, and North America. In New Mexico and southern Colorado, it is called plumajillo (Spanish for 'little feather') from its leaf shape and texture. [7]

Yarrow is a good herb to have on hand to treat winter colds and flu; a hot cup of yarrow tea makes you sweat and helps the body expel toxins while reducing fever.

The extracts of *Achillea millefolium* exerted significant anti-inflammatory, antipyretic and analgesic effects. Also potentiated the sleeping time of thiopental sodium in mice.[8]

Valerian:

Valerian is a perennial plant that is native to Europe and grows up to 2 feet tall. It is grown to decorate gardens but also grows wild in damp grasslands. Straight, hollow stems are topped by umbrella-like heads. Its dark green leaves are pointed at the tip and hairy underneath. Small, sweet-smelling white, light purple or pink flowers bloom in June. The root is light grayish brown and has little odor when fresh. Valerian has been used to ease insomnia, anxiety, and nervous restlessness since the second century A.D. It became popular in Europe in the 17th century. It has also been suggested to treat stomach cramps. Some research -- though not all -- does suggest that valerian may help some people with insomnia. Germany's Commission E approved valerian as an effective mild sedative and the United States Food

and Drug Administration listed valerian as "Generally Recognized As Safe" (GRAS).(9)

Vitis vinifera :

It is a species of *Vitis*, native to the Mediterranean region, central Europe, and southwestern Asia, from Morocco and Portugal north to southern Germany and east to northern Iran. (10) Fruits of *Vitis vinifera* have been used for thousands of years because of their nutritional and medicinal benefits. They are rich in sugars, flavonoids, anthocyanins and proanthocyanins, organic acids, tannin, mineral salts and vitamins. (11)

Camellia sinensis:

heaceae. Tea is the most consumed drink in the world after water. Green tea is a 'non-fermented' tea and contains more catechins than black tea or oolong tea. Catechins are in vitro and in vivo strong antioxidants. In addition, its content of certain minerals and vitamins increases the antioxidant potential of this type of tea. Presently, it is cultivated in at least 30 countries around the world. Tea beverage is an infusion of the dried leaves of *Camellia sinensis*. It is a widely used medicinal plant by the trials throughout India, China and popular in various indigenous system of medicine like Ayurveda, Unani and Homoeopathy Green tea has been consumed throughout the ages in India, China, Japan and Thailand.

Traditional uses of green tea include treating flatulence (gas), regulating body temperature and blood sugar, promoting digestion and improving mental processes. As an herbal remedy, green tea is often recommended to ease stomach discomfort, vomiting and to stop diarrhea. The antibacterial action of tea is useful in treating infections and wounds. (12)

The chemical components of green tea chiefly include polyphenols, caffeine and amino acids. Tea also contains flavonoids, compounds reported to have anti-oxidant properties having many beneficial effects. Tea flavonoids reduce inflammation, have

antimicrobial effects and prevent tooth decay. Consumption of tea may have diuretic effects due to the caffeine. A related compound found in tea is theophylline, a licensed medicine for the treatment of respiratory diseases such as asthma. (13)

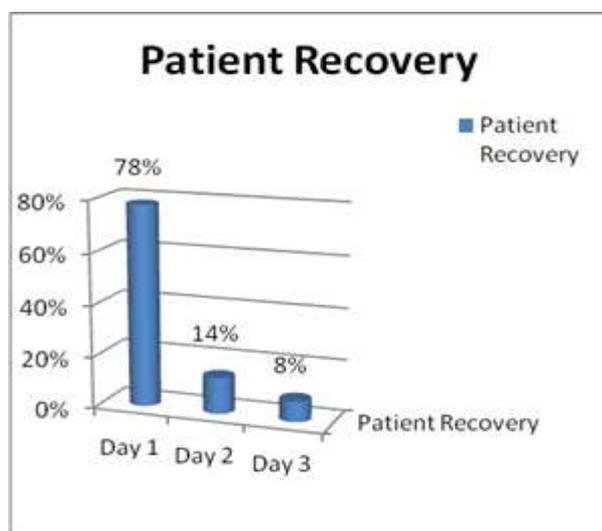
RESULTS

The overall results show that, out of 50 patients, all patients were recovered within 3 days at a dose of 2-3 sachets/day.

78% patients recovered on 1st day

14% patients recovered on 2nd day

8% patients recovered on 3rd day having fever more than 102°F.



CONCLUSION

The study result suggests that the trial formulation was quite effective in the management of pyrexia associated with upper respiratory tract infection. No adverse effects were observed during the treatment in this study. Hence it infers that trial drug is safe, and effective in the treatment of pyrexia associated with upper respiratory tract infection including cough, cold and flu.

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