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*Full Length Research Paper*

# Clinical evaluation of herbal coded formulation Pharinjaline in the treatment of Pharyngitis and Sore throat

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**This study was conducted to evaluate the efficacy of herbal coded formulation (Pharinjaline) compared with erythromycin for the treatment of sore throats and acute pharyngitis. One hundred patients with sore throat and pharyngitis were randomly divided into two groups, 50 in each group. Test group was treated with Pharinjaline and control group was treated with erythromycin. The effect of both drugs for the treatment of sore throats and acute pharyngitis were seen before and after treatment. Comparison of data recorded by the physician on the variables showed significant differences between test and control groups ($p < 0.05$). The efficacy of the test treated medication (Pharinjaline) was superior as $p = 0.03$. Pharinjaline is more effective than the Erythromycin in the treatment of sore throat and acute pharyngitis**

**Key words:** Pharyngitis, phainjaline, erythromycin, efficacy, sore throats.

## INTRODUCTION

Pharyngitis and sore throat most often are caused by direct infection of the pharynx (pharyngitis), primarily by viruses or bacteria (Robert et al. 2002; Lawrence et al. 2001). The pharynx is responsible for adjoining the nasal cavity and the oral cavity to the larynx (which belongs to the respiratory system) and the esophagus (which belongs to the digestive system (Gray et al. 1992, Sinnatamby, 1999; John, 2000). There are many agents which cause pharyngitis. Viral infections account for approximately 70% of all pharyngitis, with bacteria causing 20 to 30% of pharyngitis and 30-40% idiopathic. There is no clinical evidence that bacterial sore throats are more severe than viral ones or that the duration of the illness is significantly different in either case (Barbara et al. 2006). Clinical presentation of pharyngitis generally includes sudden onset of throat pain, difficulty in swallowing and fever higher than 101 degree Fahrenheit, tender anterior cervical nodes, and soft palatal petechiae, congestions over the posterior pharynx, tonsillar enlargement and purulent tonsillar exudate. There are some atypical symptoms which may also be present with the infected individual such as mouth breathing, nausea, vomiting, abdominal pain, and diarrhea (Pechère et al. 2004; Peltola, 1982).

## MATERIAL AND METHODS

This is a case control direct, unicenter, prospective randomized authentic allopathic controlled, two arm parallel group clinical trial. The clinical assessment included the improvement cough, fever, odynophagia, tender anterior cervical nodes, and tonsillar swelling or exudate.

**Table 1.** Age group distribution.

| Age Group | Treatment Group | | Total (n) |
|---|---|---|---|
| | Test (n) (Pharinjaline) | Control (n) (Erythromycin) | |
| 18 – 21 Years | 4 | 1 | 5 |
| 22 – 25 Years | 8 | 2 | 10 |
| 26 – 29 Years | 4 | 0 | 4 |
| 30 – 33 Years | 8 | 2 | 10 |
| 34 – 37 Years | 9 | 13 | 22 |
| 38 – 41 Years | 10 | 12 | 22 |
| 42 – 45 Years | 6 | 16 | 22 |
| 46 – 50 Years | 1 | 4 | 5 |
| Total | 50 | 50 | 100 |

**Table 2.** Fever in Total Patients at Baseline.

| Complaint at Baseline | | Treatment Group Test (Pharinjaline) | Control (Erythromycin) | Total (n) | p value |
|---|---|---|---|---|---|
| **Fever** | 100 to < 101 | 4 | 4 | 8 | |
| | 101 to < 102 | 20 | 20 | 40 | |
| | 102 to < 103 | 26 | 21 | 47 | 0.058 |
| | 103 to < 104 | 0 | 5 | 5 | |
| | Total | 50 | 50 | 100 | |

**Table 3.** Fever in Total Patients after Treatment.

| Complaint at Baseline | | Treatment Group | | Total (n) | P value |
|---|---|---|---|---|---|
| | | Test (Pharinjaline) | Control (Erythromycin) | | |
| **After** | 98 to < 99 | 50 | 49 | 99 | |
| **Treatment** | Above 99 | 00 | 01 | 01 | 1.00 |
| | Total | 50 | 50 | 100 | |

## Subjects

One hundred patients, who had no health problem records in the physical check up, participated in this study. The ethics committee at Hamdard University Karachi approved the study protocol. All subjects signed informed consent documents. Sample size estimated in clinical assessment on pharyngitis and sore throat has been carried out based on general physical examination, general appearance of the patients, age, sex, and local examination of the mouth and throat in a pilot study at Shifa ul Mulk Memorial Hospital. Trial was conducted on 100 patients suffering from pharyngitis and sore throat from both groups (50 patients from control and 50 from experimental group) between ages of 18 to 50 years irrespective of socioeconomic status (Table 1, 2 and 3).

## Sample selection

The sample was selected from the out patient department registered and enrolled in Shifa ul Mulk Memorial Hospital and on the basis of clinical sign and symptoms

**Table 4.** Odynophagia in total patients at baseline.

| Complaint at Baseline | | Treatment Group | | Total | P value |
|---|---|---|---|---|---|
| | | Test (Pharinjaline) | Control (Erythromycin) | (n) | |
| **Odynophagia** | Severe | 16 | 17 | 33 | 0.695 |
| | Moderate | 30 | 31 | 61 | |
| | Mild | 4 | 2 | 6 | |
| | Total | 50 | 50 | 100 | |

**Table 5.** Odynophagia in total patients at after treatment.

| Complaint at After Treatment | | Treatment Group | | Total | p value |
|---|---|---|---|---|---|
| | | Test | Control | (n) | |
| **Odynophagia** | Complete Improvement | 48 | 41 | 89 | 0.02 |
| | Mild Odynophagia | 02 | 09 | 11 | |
| | Total | 50 | 50 | 100 | |

**Table 6.** Tonsillar Pillar in Total Patients at Baseline.

| Complaint at Baseline | | Treatment Group Test (Pharinjaline) | Control (Erythromycin) | Total (n) | P value |
|---|---|---|---|---|---|
| **Tonsillar Pillar** | Congested | 33 | 28 | 61 | 0.581 |
| | Exudated | 09 | 11 | 20 | |
| | Normal | 08 | 11 | 19 | |
| | Total | 50 | 50 | 100 | |

and fulfilling the pharyngitis and sore, inclusion and exclusion criteria were selected. Among this population, all the patient suffering from pharyngitis and sore throat were interviewed immediately and upon their consent to participate they were grouped as test and control groups. The analysis and evaluation on an intention to treat basis was included and only those participants who were willing to undergo treatment and were willing as well to attend all the follow up visits during the clinical trial were chosen. The 100 patients were randomized to the Pharinjaline and Erythromycin groups: 50 were treated with coded herbal formulation Pharinjaline and 50 were treated with Erythromycin ( Table 4, 5 and 6).

**Data collection**

Data collected for this research work included filling of clinical trial proforma through personal interview, personal

**Table 7.** Tonsillar Pillar in Total Patients at After Treatment.

| Complaint at After Treatment | | Treatment Group | | Total | P value |
|---|---|---|---|---|---|
| | | Test | Control | (n) | |
| **Tonsillar Pillar** | Complete Improvement | 42 | 34 | 76 | |
| | Congested | 00 | 05 | 05 | 0.02 |
| | Total | 42 | 39 | 81 | |

observation and use of case record, file and documents. The designed clinical trial proforma specified the clinical feature and information to be filled by the physician for record and utilized in statistical assessment.

**Statistical analysis**

Statistical analysis were performed using SPSS and excel software, the Chi Square Test was determined. All differences were considered statistically significant by generating a 'p-value' from test
statistics. The significant result with 'p-value' less than 0.05 was considered as statistically significant.

**Inclusion Criteria**

The cases were selected on the following lines:
The patients suffering from pharyngitis and sore throat
Patients living in Gadap Town, Karachi
Patients having no obvious pathological finding on routine examination
All socioeconomic classes including lower middle and higher (Table 7).
Male and female patients between 18 to 50 years of age

**Exclusion Criteria**

**The major exclusion criteria for this trial were**

Patients belonging to the distant area outside Karachi were excluded because of inherent difficulty in follow up.
Chronic and secondary infectious cases were excluded.
Patients having chronic infections e.g. tuberculosis, leprosy or neoplastic events in the medical history were considered reason for exclusion.
Patient having history of adverse reaction to any of the study drugs

**Patient characteristics**

All of the patients recruited in this study were categorized in different class interval ranging from 18 to 50 years of age. All patients had one or more pretreatment symptoms of Pharyngitis and sore throat.

## DISCUSSION

Products from natural sources have been replaced because of their efficacy and fewer and no side effects (Bertels, et al., 1999; Henkel, et al., 1999; Verdine, 1996). The coded herbal formulation Pharinjaline for Pharyngitis and sore throat treatment comprises of, Aconitum heterophyllum and Atropa acuminate. The medicinal plants Aconitum heterophyllum and Atropa acuminate have been used traditionally in medicine for decades. Their anti inflammatory, antispasmotics and anti-pyretic effects have been used very effectively other than their use in coryza, and other illnesses. It was so discovered with research and clinical trial that the two new compounds isolated from the Aconitum heterophyllum displayed a significant antibiotic activity. These two compounds are 6-dehydroacetylsepacontinine and 13-hydroxylappacontine along with other known norditerpenoid alkaloids namely lycoctonine, delphatine and lappaconitine(Manzoor et al, 2008). This comparative study was conducted to explore the pharyngitis and sore throat patients with herbal formulation as test drug and allopathic as control drug to assess their efficacy.

## CONCLUSION

Pharinjaline (test drug) is more effective than the Erythromycin(control drug). in the treatment of pharyngitis and sore throat. Control drug showed lesser efficacy than the test drug in its compliance to treat pharyngitis and sore throat. Moreover the patient's satisfaction to cure pharyngitis and sore throat was very well received in patients prescribed test drug and found greater acceptability. The results of the current study demonstrate that treatment with Pharinjaline (test drug) reduces signs and symptoms as well as eradication of infection and that these effects are significantly greater than those produced by the commonly used erythromycin. The efficacy of Pharinjaline (test drug) in subjects with liver impairment is promising and warrants further study.

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