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A Single-Blind, Randomized, Clinical Study of THROZEN (Cough Lozenges Formulation) for the Treatment of Sore Throat and Cough

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Abstract

Objective: THROZEN (Cough lozenges formulation) having herbal ingredients usedfor sore throat and cough mainly contains Anacyclus pyrethrum, zinc and menthol. Zinc is effective against cough and sore throat and also shortens the duration of infection. Thus zinc reduces sufferings caused due to existing infection. Zinc can stop viruses from multiplying, thus it has a static action which halts progress of the infection. Anacyclus pyrethrum is effective against sore throat as well as cough, dry mouth and redness of throat. In the present study, clinical evaluation of THROZEN cough lozenges has been done in human subjects.

Method: Single-blind, Randomized, clinical study of THROZEN (cough lozenges formulation) was done on 108 subjects with existing cough and sore throat condition at two different clinical sites. The subjects were given the cough lozenges after they were enrolled in the study and were followed up for a period of seven days. The sore throat severity along with cough, dry mouth, itching of throat, voice quality, redness of throat and hoarseness were recorded on day 0, 7th day and on the 14th day of treatment during follow-up visits.

Results: All the subjects undergone treatment have shown a significant decrease ($p<0.001$) in the frequency and severity of the sore throat and cough. No adverse effects were observed for any subjects. Assessment was based on improvement in symptoms, acceptability and overall efficiency and safety as reported by the physician and the subjects.

Conclusion: THROZEN proved to be an effective and safe cough lozenges that is highly acceptable by subjects enrolled in the study who were suffering from sore throat and cough.

Keywords: THROZEN; Cough lozenges; Sore throat; Dry mouth; Itching of throat; Redness of throat; Single-blind; Randomized; Clinical study

Introduction

Depending upon the severity, cough is generally defined as acute, subacute or persistent. Several pathologies might be the cause for persisting cough which generally lasts more than 8 weeks. Cough may be a manifestation of any lung and bronchial disease. Smoking, treatment with ACE-inhibitors, GERD (Gastroesophageal Reflux Disease), asthma, chronic bronchitis and upper airway cough syndrome (UACS) due to a variety of rhinosinus conditions are the most common causes of coughing [1-3].

Cough variant asthma (CVA) is a form of asthma, wherein cough is the sole symptom. CVA is one of the most common cause which leads to chronic cough. About 30 to 40% of adult patients with CVA, may progress to classic asthma, unless adequately treated. A wide range of treatments such as phytotherapies, hydrotherapies and Traditional Chinese Medicine (TCM) involve use of herbal medicines. Few herbs also have applications in conventional medicine. Although herbal treatments have an ancient history of use in varied cultures, randomized controlled trial (RCT) data on their effectivity is generally lacking [1-3]. Cough is the most common symptom for which patients seek medical attention as the profound and adverse effect of cough affects their quality of life [4].

Direct infection of the pharynx (pharyngitis), primarily caused by viruses or bacteria is most often the cause of sore throat. There is no evidence that bacterial sore throats are more severe than viral ones or that the duration of the illness is significantly different in either case. An inflammatory process in the pharynx, tonsils or nasopharynx often leads to acute sore throat. Acute sore throat is itself a symptom and thus the pain or associated discomfort in the pharynx is not always an impact of an infectious agent. Conversely, pharyngeal area of asymptomatic patients often harbours infectious agents. Studies on sore throat along with identification of wide spectrum of associated bacterial and viral infectious agents, either alone or mixed in both symptomatic as well as asymptomatic children or adults during different seasons are lacking apparently. An occurrence of sore throat as a complaint defines a sore throat episode. This soreness complaint is generally described by the patient as pain in the throat with and without the effort of swallowing [5-7].

Some herbal extracts have been proven safe with bronchodilatory as well as mucolytic effects even in children [8,9]. Ivy/primrose/thyme-based preparations are the herbal cough treatments with proven clinical efficacy and are recommended as expectorants in current European guidelines [2,10,11].

THROZEN cough lozenges contain key herbal ingredients such as Anacyclus pyrethrum, zinc and menthol. No chemical cough suppressants included hence people allergic to drugs can consume it. The effectivity of zinc ions are not restricted to the pharyngeal region. There is no indication that the effectivity of zinc lozenges on nasal symptoms is less than it's effectivity on the symptoms of the pharyngeal region, where the exposure to released zinc ions is comparatively more. Zinc can inhibit rhinovirus replication and also has activity against other respiratory viruses such as respiratory syncytial virus. Zinc lozenges are slowly dissolved in the pharyngeal region and the effects of zinc seem to be local. Anacyclus pyrethrum is also effective for treatment of cough, sore throat, dry mouth and redness of throat. The effects on cough-related symptoms were addressed on a verbal rating scale. The herbal formulations are generally considered safe and effective as they are derived from natural ingredients prescribed in the ancient herbal system of medicines and known to be giving long lasting relief from all kinds of coughs [12-16].

Materials and Methods

Subjects

In the present study, the efficacy and safety of THROZEN cough lozenges formulation has been evaluated by enrolling the patients of age of 18 to 65 years suffering from sore throat and/or cough issues. Different parameters like degree of sore throat, cough, dry mouth, itching of throat, voice quality, redness of throat and hoarseness were evaluated during enrollment as well as during 1st week and 2nd week follow up visits.

Study procedures

Participant recruitment and screening: Patients were recruited amongst those attending the clinical research centers. Patients were given information about their disease condition, procedures to be followed, experimental nature of treatment, alternative treatments and potential risks. The above information has been given verbally in a pre-screening consultation with the investigator. Patients who have given their signed informed consent were enrolled in the study. After enrollment, screening has been done. Screening procedures include general information, physical examination and medical history.

Inclusion and exclusion criteria: Screening and inclusion criteria to conduct the study are,

- Normal healthy human volunteers with cough and/or sore throat issues should be included.
- Patient with sign and symptoms of viral or bacterial throat infection.
- Patients between the age 18 to 65 years from both sex.
- Patients willing to sign an informed written consent and comply with visit schedules.
- Patients must be able to communicate effectively with study personnel.
- Patients were excluded from the study on the basis of exclusion criteria:
- Known positive status and known history for HIV, active hepatitis B or hepatitis C.
- Pregnant or breast feeding women.
- Volunteers should not have any chronic disease, especially respiratory tract disorder and tuberculosis volunteers even with past history should not be included.
- Subjects on any other experimental treatment within 07 days of the first dose of study drug or who have not recovered from the side effects of such therapy.
- Patient have history of hospitalized treatment before 07 days.

Early withdrawal criteria

Patients may withdraw from the study at any given time, and for any of the following reasons: If any adverse reaction or side effect is observed during the study, then the patient may be withdrawn from the study as per investigator's decision. If the patient is withdrawing himself/herself from the study, then it is as per his/her right to withdraw as mentioned in informed consent form of the study.

Experimental design: A single blinded clinical trial was conducted in which only the researcher but not the subjects knew about which active medication or treatment were given to them. Clinical trial was conducted at more than one clinical site. After enrollment and screening, subjects who were fitting in inclusion criteria have been dispensed with one week dose of cough lozenges. The dose of THROZEN cough lozenges was 2 cough lozenges per day divided in day and night schedule. Hence, 14 cough lozenges had been dispensed to each subjects as a part of 1st week treatment.

During 1st follow up visit, various parameters like sore throat, cough, dry mouth, itching of throat, voice quality, redness of throat, hoarseness have been checked and scored as per below mentioned scoring pattern:

- Score 0 is no symptom,
- Score 1 is mild,
- Score 2 is moderate,
- Score 3 is severe and
- Score 4 is too much severe

After recording the observation for respective subject, each subject was given additional dose of 14 cough lozenges for the treatment of 2nd week. After completion of 2nd week treatment, respective subject had to visit to their respective clinical site.

Statistical Analysis

Compiled results were tabulated and represented in Table 1 as Mean ± SEM of secondary efficacy variables on 0, 7th and 14th day of treatment with THROZEN cough lozenges. Paired t-test was applied to see difference in effect in respective parameter at the end of 1st week and 2nd week treatment in comparison to that of zero day (enrollment day). Value, $p<0.05$ was considered as statistically significant when compared to the value with zero day (enrollment day) data.

Results and Discussion

Total of 230 subjects were preliminary screened. All these subjects were screened through inclusion and exclusion screening criteria's, from those 108 subjects were enrolled in the study. 08 subjects discontinued the study willingly after 7 days course due to recovery from symptoms of secondary variable parameters. Remaining all 100 patients, completed full 14 days of therapy and study procedures. All study procedures were completed at each visit for each subject. Not a single subject experienced any adverse effect.

S. No.	Secondary Efficacy Variable	Mean Value ± SEM (Standard error of the mean)		
		0 day	7th day	14th day
1	Cough	3.34 ± 0.068*	1.83 ± 0.101*	0.04 ± 0.019*
2	Sore throat	3.00 ± 0.076*	1.90 ± 0.078*	0.04 ± 0.019*
3	Dry mouth	3.02 ± 0.079*	1.75 ± 0.088*	0.05 ± 0.021*
4	Itching of throat	3.19 ± 0.070*	1.68 ± 0.095*	0.03 ± 0.017*
5	Voice quality	2.89 ± 0.068*	1.65 ± 0.078*	0.07 ± 0.025*
6	Redness of throat	2.99 ± 0.070*	1.65 ± 0.088*	0.07 ± 0.025*
7	Hoarseness	3.00 ± 0.065*	1.63 ± 0.098*	0.06 ± 0.023*
Total no. of subjects=100 *p<0.0001 using paired t- test when compared respective data before and after treatment with THROZEN cough lozenges				

Table 1: Summary table of results of statistics.

All of the subjects who continued till 07 days or completed the study course for 14 day have given positive response towards the investigation product and were satisfied with the treatment provided. Subjects with mild/moderate secondary variable parameters showed results within 07 days of treatment and discontinued the study voluntarily.

All the subjects enrolled in the study have shown a significant decrease ($p<0.0001$) in the frequency and severity of the sore throat and cough (Table 1). Assessment was based on improvement in symptoms, acceptability and overall efficiency and safety as reported by the physician and the subjects.

Conclusion

The Clinical trial of THROZEN Cough lozenges was completed successfully. In study, total numbers of patients screened were 230 and 108 number of subjects were enrolled for the study. A total of 8 numbers of subjects discontinued after 07 days study willingly. No any adverse effects observed. Subjects showed positive response during the treatment period and the effects of cough lozenges were found satisfactory. Thus, we can conclude that THROZEN is clinically proven for its efficacy and safety.

Declarations

Ethics approval and consent to participate

Ethical principles in the Helsinki Declaration and as specified in the ICH-GCP Guidelines and ethical guidelines of ICMR, New Delhi has been adopted. No patient without his/her informed consent has been recruited for the study. The protocol of this study has been approved with study code no. AD/CSP/2018/001-01 by ACEAS-Independent Ethics Committee (CDSCO Registration No. ECR/281/Indt/GJ/2017 and OHRP US DHSS Registration No. IRB00011045) and the protocol has been registered on Clinical Trial Registry of India (CTRI), CTRI No. CTRI/2018/08/015547.

Competing Interests

I would like to declare that there is no conflict of interest by publishing this article.

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Authors Contributions

I have conceptualized the entire study reported in this article.

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