

Efficacy of EPs 7630 in acute non-streptococcal tonsillopharyngitis

Submission date 14/06/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/06/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/10/2007	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UM002

Study information

Scientific Title

Study objectives

This study was a prospective, monocentre, randomised, open clinical pilot trial, comparing the efficacy of the herbal medicine EPs 7630 versus symptomatic therapy in patients with acute, non-streptococcal tonsillopharyngitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Acute, non-streptococcal tonsillopharyngitis

Interventions

60 patients were randomised to receive either:

1. Herbal remedy EPs 7630, 20 drops thrice daily, or
2. Symptomatic therapy (gargling with fruit vinegar and lukewarm water, Priessnitz compresses).

The duration of individual treatment lasted over a maximum of 10 days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

EPs 7630

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/1997

Completion date

30/04/1997

Eligibility

Key inclusion criteria

The study took place between March and April 1997. It is terminated. Patients, who met the following inclusion criteria, were suitable for the trial:

1. Age 6-10 years
2. Acute exsudative tonsillopharyngitis
3. Duration of symptoms less than 48 h
4. No Group A Beta Hemolytic Streptococcus (GABHS)-infection
5. Tonsillopharyngitis Severity Score (TSS) 6 or more points, and
6. Informed consent in writing by legal guardians who were able to understand the nature, meaning and consequences of the trial

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/1997

Date of final enrolment

30/04/1997

Locations

Countries of recruitment

Germany

Study participating centre
Director Research Center HomInt
Karlsruhe
Germany
76202

Sponsor information

Organisation
ISO Arzneimittel GmbH & Co KG (Germany)

Sponsor details
Bunsenstrasse 6-10
Ettlingen
Germany
76275

Sponsor type
Industry

Website
<http://www.iso-arznei.de>

ROR
<https://ror.org/045xrc244>

Funder(s)

Funder type
Not defined

Funder Name
ISO Arzneimittel GmbH & Co KG

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration