Efficacy of EPs 7630 compared to placebo in children with acute non-streptococcal tonsillopharyngitis

Submission date Recruitment status Prospectively registered 26/03/2003 No longer recruiting [] Protocol Statistical analysis plan Overall study status Registration date 26/03/2003 Completed [X] Results [] Individual participant data Last Edited Condition category 15/10/2008 Respiratory

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers UM012

Study information

Scientific Title

Study objectives

Not provided at time of registration

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 tonsillopharyngitis

Interventions

124 Children were randomised to receive either:

- 1. Herbal remedy EPs 7630, 20 drops three times daily
- 2. Placebo, 20 drops three times daily.

The duration of individual treatment lasted over a maximum of 6 days.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

01/06/2003

Eligibility

Key inclusion criteria

Patients who met the following inclusion criteria were suitable for the trial:

- 1. Age 6 10 years, acute tonsillopharyngitis, duration of complaints less than 48 hours, negative dip-and-react-test test for beta-hemolytic streptococcus and severity of symptoms greater than or equal to 8 points
- 2. In addition legal guardians had to sign an informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

124

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

01/06/2003

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

Industry

Funder Name

ISO Arzneimittel GmbH & Co KG (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/09/2003		Yes	No