

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

Submission date 26/03/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/03/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/10/2021	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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
UM007.2

Study information

Scientific Title

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

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

78 Children were randomised to receive either:

1. Herbal remedy EPs 7630, 20 drops per hour during the first 1 - 2 days, followed by 20 drops three times daily
2. Placebo, 20 drops per hour during the first 1 - 2 days, followed by 20 drops three times daily

The duration of individual treatment lasted over a maximum of 6 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

01/01/2003

Completion date

31/12/2003

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 h, negative dip-and-react-test test for β -hemolytic streptococcus and severity of symptoms ≥ 6 points
2. In addition legal guardians had to sign an informed consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

78

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2003

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			07/10/2021	Yes	No