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

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

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
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

Ukraine

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