ISRCTN86579667 https://doi.org/10.1186/ISRCTN86579667

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

Submission date	Recruitment status	[_] Prospectively registered
26/03/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2021	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marianne Heger

Contact details
Director Research Center HomInt
PO Box 41 02 40
Karlsruhe
Germany
76202

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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 ß-hemolytic streptococcus and severity of symptoms ≥6 points
2. In addition legal guardians had to sign an informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

ROR
https://ror.org/045xrc244

Funder(s)

Funder type
Industry

Funder Name
ISO Arzneimittel GmbH & Co KG (Germany)

Results and Publications

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