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Efficacy of EPs 7630 in acute non-streptococcal tonsillopharyngitis

Submission date	Recruitment status	[_] Prospectively registered
14/06/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2002	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/10/2007	Ear, Nose and Throat	[_] Record updated in last year

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/1997

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)

ROR
https://ror.org/045xrc244

Funder(s)

Funder type
Not defined

Funder Name
ISO Arzneimittel GmbH & Co KG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration