

Efficacy of EPs 7630 compared to placebo in the treatment of acute bronchitis

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 07/09/2007	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
UM028

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 bronchitis

Interventions

205 patients were randomised to receive either:

1. Herbal remedy EPs 7630, 30 drops three times daily
2. Placebo, 30 drops three times daily.

The duration of individual treatment lasted over a maximum of 7 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. Aged greater than or equal to 18 years, acute bronchitis, duration of complaints less than 48 hours, and total score of bronchitis-specific symptoms greater than or equal to 5 points
2. In addition patients had to sign an informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

205

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	Results	01/10/2003		Yes	No