

Efficacy of EPs 7630 compared to N-acetylcysteine (ACC) in children with 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 type="checkbox"/> Results
Last Edited 07/09/2007	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
UM009

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute bronchitis

Interventions

215 Children were randomised to receive either:

1. Herbal remedy EPs 7630, 20 drops three times daily
2. ACC, 200 mg twice 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, N-acetylcysteine (ACC)

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 - 12 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 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