

# Efficacy of EPs 7630 compared to N-acetylcysteine (ACC) in children with acute bronchitis

<b>Submission date</b> 26/03/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/09/2007	<b>Condition category</b> 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

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Germany  
76202

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## 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

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 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. 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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

215

**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