Clinical trial results:
Open label clinical trial to determine the blood ethanol concentration following repeated administration of Bronchicum Elixir to children (1 to 12 years) with acute bronchitis.

Summary

EudraCT number	2009-014904-73
Trial protocol	DE
Global end of trial date	01 December 2010

Results information

Result version number	v1 (current)
This version publication date	02 May 2025
First version publication date	02 May 2025

Trial information

Trial identification

Sponsor protocol code	CAS/K/00409

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cassella-med GmbH & Co. KG
Sponsor organisation address	Gereonsmuehlengasse 1, Cologne, Germany, 50670
Public contact	Clinical Operations, Cassella-med GmbH & Co.KG, clinical.operations@klosterfrau.de
Scientific contact	Clinical Operations, Cassella-med GmbH & Co.KG, clinical.operations@klosterfrau.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 April 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2010
Global end of trial reached?	Yes
Global end of trial date	01 December 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this open label clinical trial is to determine if blood ethanol concentration reaches a critical value (0,125‰) after repeated administration of a dose of the IMP to children in the age between 1 and 12 years.

Protection of trial subjects:

Each subject (depending on age) and their legal guardians were fully informed of all aspects of the study and provided informed consent prior to start of any study procedures. Subjects and/or their legal guardians could withdraw from treatment at any time and for any reason. No specific additional measures were required to minimize distress given the nature of study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 March 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	3
Children (2-11 years)	13
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All patients came from the patient pool of the investigator's practice.

Pre-assignment

Screening details:

Subjects were eligible for inclusion, if the main criteria were met: -acute illness for a maximum of 48 hours; - Bronchitis Severity Score (BSS) ≥ 5 points; - infants and children aged 1 to 12 years; - the custodial parent(s) give their written informed consent

Period 1

Period 1 title	overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Age Group I (1-4 years old)

Arm description: -

Arm type	age
Investigational medicinal product name	Bronchicum Elixir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

2.5 ml six times a day

Arm title	Age Group II (5-12 years old)

Arm description: -

Arm type	age
Investigational medicinal product name	Bronchicum Elixier
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

7.5 ml four times a day

Number of subjects in period 1	Age Group I (1-4 years old)	Age Group II (5-12 years old)
Started	12	4
Completed	12	4

Baseline characteristics

Reporting groups	
Reporting group title	Age Group I (1-4 years old)
Reporting group description: -	
Reporting group title	Age Group II (5-12 years old)
Reporting group description: -	

Reporting group values	Age Group I (1-4 years old)	Age Group II (5-12 years old)	Total
Number of subjects	12	4	16
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	3	0	3
Children (2-11 years)	9	4	13
Gender categorical Units: Subjects			
Female	6	2	8
Male	6	2	8

Subject analysis sets	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The ITT set consists of all subjects who were randomized and applied at least one dose of study medication. For this study all subjects were included in the safety analysis.

Reporting group values	ITT		
Number of subjects	16		
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	3		
Children (2-11 years)	13		
Gender categorical Units: Subjects			
Female	8		
Male	8		

End points

End points reporting groups

Reporting group title	Age Group I (1-4 years old)
Reporting group description: -	
Reporting group title	Age Group II (5-12 years old)
Reporting group description: -	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The ITT set consists of all subjects who were randomized and applied at least one dose of study medication. For this study all subjects were included in the safety analysis.

Primary: Blood alcohol determination (after 45 min)

End point title	Blood alcohol determination (after 45 min)

End point description:

End point type	Primary

End point timeframe:

At the second visit, each patient was given the prescribed dose of Bronchicum Elixir for the age group and a blood sample was taken after 45 minutes.

End point values	Age Group I (1-4 years old)	Age Group II (5-12 years old)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	4		
Units: percent weight/volume				
arithmetic mean (standard deviation)	0.0022 (± 0.0038)	0.0048 (± 0.0096)		

Statistical analyses

Statistical analysis title	95% confidence intervals (tolerance ranges)

Statistical analysis description:

exploratively examined and descriptively analyzed

Comparison groups	Age Group I (1-4 years old) v Age Group II (5-12 years old)
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Bronchitis Severity Score (BSS) - relative reduction to V1

End point title	Bronchitis Severity Score (BSS) - relative reduction to V1

End point description:

End point type	Secondary

End point timeframe:

Determination of the therapeutic effect of the investigational product in acute bronchitis by comparing the Bronchitis Severity Score at V1 and V3

End point values	Age Group I (1-4 years old)	Age Group II (5-12 years old)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: %				
arithmetic mean (standard deviation)	82.9 (± 28.2)	87.5 (± 25.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: V1 (Day 1) to V3 (Day 7-9)	
Assessment type	Systematic

Dictionary used	
Dictionary name	unknown
Dictionary version	0

Reporting groups	
Reporting group title	Intention to treat

Reporting group description: -

Serious adverse events	Intention to treat		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Intention to treat		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 16 (31.25%)		
Investigations			
Worsening of symptoms			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
General disorders and administration site conditions			
Foreign body ingestion			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Gastrointestinal disorders			

Vomiting subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported