



Clinical trial results:

Ambroxol inhalation for mucus clearance in palliative care patients - a randomized placebo-controlled double-blind pilot study.

Summary

EudraCT number	2020-004377-44
Trial protocol	AT
Global end of trial date	22 March 2023

Results information

Result version number	v1 (current)
This version publication date	27 May 2026
First version publication date	27 May 2026

Trial information

Trial identification

Sponsor protocol code	Ambroxpall
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Eva Katharina Masel, Med. Univ. Wien, Innere Med. I, Abt. f. Palliativmedizin, +43 14040077800, eva.masel@meduniwien.ac.at
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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	23 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 March 2023
Global end of trial reached?	Yes
Global end of trial date	22 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main study objective is to assess subjective respondent ratings.

Protection of trial subjects:

To assess the benefit of an ambroxol-inhalation versus placebo in patients with hypersecretion treated in a palliative care unit

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 August 2021
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	Austria: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	5
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the division of palliative medicine of the medical university of vienna

Pre-assignment

Screening details:

Demographic data, ECOG Performance State, PGIC-Score, Spirometry, Mucus weight, SPO2

Period 1

Period 1 title	Medication (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	active phase
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Arm description:

The active arm received 10ml ambroxol hydrochloride twice daily for five days

Arm type	Active comparator
Investigational medicinal product name	Ambroxol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

10ml Ambroxol twice daily for 5 days

Arm title	Placebo
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Arm description:

The placebo arm received 10ml sodium chloride inhalation twice daily for five days

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

10ml sodium chloride inhalation twice daily for five days

Number of subjects in period 1	active phase	Placebo
Started	4	4
Completed	3	4
Not completed	1	0
Patient preference	1	-

Baseline characteristics

Reporting groups

Reporting group title	active phase
Reporting group description: The active arm received 10ml ambroxol hydrochloride twice daily for five days	
Reporting group title	Placebo
Reporting group description: The placebo arm received 10ml sodium chloride inhalation twice daily for days	

Reporting group values	active phase	Placebo	Total
Number of subjects	4	4	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	2	5
From 65-84 years	1	2	3
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	3	1	4
Male	1	3	4

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Intention-to-treat
Subject analysis set description: Patients in a palliative setting were assessed by the PGIC score (primary endpoint) in regard to the influence of inhalation therapy on their hypersecretion	

Reporting group values	Overall trial		
Number of subjects	8		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		

Adults (18-64 years)	5		
From 65-84 years	3		
85 years and over	0		
Gender categorical			
Units: Subjects			
Female	4		
Male	4		

End points

End points reporting groups

Reporting group title	active phase
Reporting group description: The active arm received 10ml ambroxol hydrochloride twice daily for five days	
Reporting group title	Placebo
Reporting group description: The placebo arm received 10ml sodium chloride inhalation twice daily for days	
Subject analysis set title	Overall trial
Subject analysis set type	Intention-to-treat
Subject analysis set description: Patients in a palliative setting were assessed by the PGIC score (primary endpoint) in regard to the influence of inhalation therapy on their hypersecretion	

Primary: PGIC score

End point title	PGIC score ^[1]
End point description:	
End point type	Primary
End point timeframe: First score day5 second score day 12	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: PGIC scores could not be collected from enough patients to perform a statistical analysis

End point values	active phase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	4		
Units: number	3	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Entire Study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There was no adverse events in this study.

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