Clinical trial results:
Bronkial respons på inhaleret Mannitol

Summary

EudraCT number	2007-003765-40
Trial protocol	DK
Global end of trial date	01 July 2008

Results information

Result version number	v1 (current)
This version publication date	17 August 2022
First version publication date	17 August 2022

Trial information

Trial identification

Sponsor protocol code	2007-003765-40

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bispebjerg Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen, Denmark, 2400
Public contact	Asger Sverrild, Bispebjerg Hospital Department of Respiratory Medicine and Infectious Diseases, 45 26259961, asger.sverrild@regionh.dk
Scientific contact	Asger Sverrild, Bispebjerg Hospital Department of Respiratory Medicine and Infectious Diseases, 45 26259961, asger.sverrild@regionh.dk

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	08 August 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 July 2008
Global end of trial reached?	Yes
Global end of trial date	01 July 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. Frequency of asthma
2. Frequency of AHR to mannitol and methacholine
3. Association between AHR to mannitol and methacholine

Protection of trial subjects:

Subjects were examined in a hospital setting following international clinical practices for all investigations

Background therapy:

None specific required

Evidence for comparator: -

Actual start date of recruitment	05 February 2007
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	Denmark: 238
Worldwide total number of subjects	238
EEA total number of subjects	238

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)	91
Adults (18-64 years)	147
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a population study - An unselected sample of 1000 young adults between the ages of 14 and 24 years was randomly drawn from the civil registration list

Pre-assignment

Screening details:

This was a population study - An unselected sample of 1000 young adults between the ages of 14 and 24 years was randomly drawn from the civil registration list

Period 1

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

Arms

Arm title	full population

Arm description:

all participants in the trial had the same investigations perfomred studying the performance of inhaled mannitol as a diagnostic tool for astma

Arm type	Experimental
Investigational medicinal product name	mannitol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

FEV1 recorded after inhalation of a 0-mg placebo capsule constituted baseline lung function. The challenge was stopped at a decrease in FEV1 of 15% or greater from baseline values or when the maximum cumulative dose of 635 mg had been administered

Number of subjects in period 1	full population
Started	238
Completed	238

Baseline characteristics

End points

End points reporting groups

Reporting group title	full population
Reporting group description:	
all participants in the trial had the same investigations perfomred studying the performance of inhaled mannitol as a diagnostic tool for astma	
Subject analysis set title	Diagnostic properties of inhaled mannitol and methacholine
Subject analysis set type	Full analysis
Subject analysis set description:	
Diagnostic properties of AHR to inhaled mannitol and methacholine in the assessment of asthma in an unselected sample of young adults	

Primary: Asthma prevalence

End point title	Asthma prevalence[1]
End point description:	
Asthma prevalence in an unselected samples of Danish young adults	
End point type	Primary
End point timeframe:	
5th of Feb 2007 to 5th of April 2008	

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: patients with a diagnosis of asthma out of the whole study population

End point values	Diagnostic properties of inhaled mannitol and methacholine			
Subject group type	Subject analysis set			
Number of subjects analysed	238			
Units: percent				
number (not applicable)	21.4			

Statistical analyses

No statistical analyses for this end point

Primary: Sensitivity - inhaled mannitol

End point title	Sensitivity - inhaled mannitol[2]
End point description:	
Sensitivity and Specificity of inhaled mannitol in diagnosing asthma in a random population sample	
End point type	Primary
End point timeframe:	
5th of Feb 2007 to 5th of April 2008	

Notes:

[2] - 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: A receiver operating characteristic (ROC) curve was constructed, plotting RDRs to mannitol and methacholine against the diagnosis of asthma.

The overall accuracy of the test was measured as the area under the ROC curve. Sensitivity and Specificity were calculated

End point values	Diagnostic properties of inhaled mannitol and methacholine			
Subject group type	Subject analysis set			
Number of subjects analysed	238			
Units: percent				
number (confidence interval 95%)	58.8 (50.7 to 62.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Sensitivity - methacholine

End point title	Sensitivity - methacholine[3]

End point description:

Sensitivity and Specificity of inhaled methacholine in an unselected sample of Danish young adults

End point type	Primary

End point timeframe:

5th of Feb 2007 to 5th of April 2008

Notes:

[3] - 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: A receiver operating characteristic (ROC) curve was constructed, plotting RDRs to mannitol and methacholine against the diagnosis of asthma.
The overall accuracy of the test was measured as the area under the ROC curve. Sensitivity and Specificity were calculated

End point values	Diagnostic properties of inhaled mannitol and methacholine			
Subject group type	Subject analysis set			
Number of subjects analysed	238			
Units: percent				
number (confidence interval 95%)	69 (57 to 78)			

Statistical analyses

No statistical analyses for this end point

Primary: Specificity - inhaled mannitol

End point title	Specificity - inhaled mannitol[4]

End point description:

Specificity of inhaled mannitol in diagnosing asthma in a random population sample of young adults

End point type	Primary

End point timeframe:

5th of Feb 2007 to 5th of April 2008

Notes:

[4] - 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: A receiver operating characteristic (ROC) curve was constructed, plotting RDRs to mannitol and methacholine against the diagnosis of asthma.
The overall accuracy of the test was measured as the area under the ROC curve. Sensitivity and Specificity were calculated

End point values	Diagnostic properties of inhaled mannitol and methacholine			
Subject group type	Subject analysis set			
Number of subjects analysed	238			
Units: percent				
number (confidence interval 95%)	98.4 (96.2 to 99.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Specificity - methacholine

End point title	Specificity - methacholine[5]

End point description:

Specificity of methacholine in diagnosing asthma in a random population sample of young adults

End point type	Primary

End point timeframe:

5th of Feb 2007 to April 2008

Notes:

[5] - 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: A receiver operating characteristic (ROC) curve was constructed, plotting RDRs to mannitol and methacholine against the diagnosis of asthma.
The overall accuracy of the test was measured as the area under the ROC curve. Sensitivity and Specificity were calculated.

End point values	Diagnostic properties of inhaled mannitol and methacholine			
Subject group type	Subject analysis set			
Number of subjects analysed	238			
Units: percent				
number (confidence interval 95%)	80 (77 to 83)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 5th of Feb 2007 to 4th of April 2008	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	9.1

Frequency threshold for reporting non-serious adverse events: 5 %

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: Cough was repored as an expected non-serious adverse event in the majority

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