Clinical trial results:
Effect of Dual Bronchodilatation on Broncholysis Testing in COPD Patients

Summary

EudraCT number	2014-002667-15
Trial protocol	AT
Global end of trial date	17 December 2014

Results information

Result version number	v1 (current)
This version publication date	21 November 2020
First version publication date	21 November 2020

Trial information

Trial identification

Sponsor protocol code	05201401

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020
Public contact	Katarzyna Wachowicz, Medical university Innsbruck, University Hospital for Internal Medicine II (Pneumology) , +43 51250423258, Katarzyna.Wachowicz@i-med.ac.at
Scientific contact	Katarzyna Wachowicz, Medical university Innsbruck, University Hospital for Internal Medicine II (Pneumology) , +43 51250423258, Katarzyna.Wachowicz@i-med.ac.at

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	17 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

A change in the FEV1 parameter (Forced Expiratory Pressure in 1 Second) value in an acute broncholysis testing (pre-brochnolysis versus post-broncholysis) is supposed to distinguish between COPD and asthmatic patients. The aim of this study is to compare the effects of a dual bronchodilator (glycopyrronium 43 µg / indacaterol 85 µg) with a standard short-acting bronchodilator (salbutamol) on changes in the FEV1 values.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	15 September 2014
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Salbutamol/ Ultibro

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ultibro Breezhaler
Investigational medicinal product code	
Other name	indacaterol maleate / glycopyrronium bromide
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Inhalation of Glykopyronium 43 microgram / 85 microgram indacaterol

Investigational medicinal product name	Salbutamol Sandoz
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

Inhalation of salbutamol 0.2 mg (2 puffs - Salbutamol Sandoz 100 micrograms) nebulized with the help of a spacer.

Number of subjects in period 1	Salbutamol/ Ultibro
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Treatment period

Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	99999	99999	
Age categorical			
"99999" is a value for 0 participants.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
"99999" is a value for 0 participants.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
"99999" is a value for 0 participants.			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Salbutamol/ Ultibro

Reporting group description: -

Primary: Change of FEV1 compared to baseline

End point title	Change of FEV1 compared to baseline[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: No subjects were included in this trial, therefore no statistical analysis was done.

End point values	Salbutamol/ Ultibro			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: FEV				
number (not applicable)	99999			

Notes:

[2] - "99999" is a value for 0 participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

15.9.2014-17.12.2014

Adverse event reporting additional description:

No patients were included in this trial, therefore o AEs and SAEs were observed.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.03

Reporting groups

Reporting group title	Salbutamol/ Ultibro

Reporting group description: -

Serious adverse events	Salbutamol/ Ultibro		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Salbutamol/ Ultibro		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No patients were included in this trial, therefore no AEs or SAEs were obsered,

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants , as it was not possible to fill in "0" for the number of included patients.

Notes: