



## 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
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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 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:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	17 December 2014
Is this the analysis of the primary completion data?	No

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

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Notes:

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**General information about the trial**

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Main objective of the trial:

A change in the FEV1 parameter (Forced Expiratory Pressure in 1 Second) value in an acute broncholysis testing (pre-broncholysis 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.

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Protection of trial subjects:

N/A

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Background therapy:

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Evidence for comparator:

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Actual start date of recruitment	15 September 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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Country: Number of subjects enrolled	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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Notes:

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**Subjects enrolled per age group**

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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

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85 years and over	0
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## 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

<b>Arm title</b>	Salbutamol/ Ultibro
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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 Glycopyrronium 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.

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

## Baseline characteristics

### Reporting groups

Reporting group title	Treatment period
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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 <sup>[1]</sup>
End point description:	

End point type	Primary
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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 <sup>[2]</sup>			
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<sup>[1]</sup>

Timeframe for reporting adverse events:

15.9.2014-17.12.2014

Adverse event reporting additional description:

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

Assessment type	Systematic
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### Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.03
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### Reporting groups

Reporting group title	Salbutamol/ Ultibro
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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 observed,

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### 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.
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Notes: