



Clinical trial results: Pharmacological effects of acute and accumulated salbutamol in relation to doping analysis

Summary

EudraCT number	2016-002819-18
Trial protocol	DK
Global end of trial date	05 November 2017

Results information

Result version number	v1 (current)
This version publication date	29 March 2020
First version publication date	29 March 2020
Summary attachment (see zip file)	2016-002819-18summary (SAL2016summary.pdf)

Trial information

Trial identification

Sponsor protocol code	WADA2016Sal
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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, CPH NV, Denmark, 2300
Public contact	Morten Hostrup, Bispebjerg University Hospital, mortenhostrup@gmail.com
Scientific contact	Morten Hostrup, Bispebjerg University Hospital, mortenhostrup@gmail.com

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	01 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 November 2017
Global end of trial reached?	Yes
Global end of trial date	05 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim is to investigate the pharmacodynamics and kinetics for acute and accumulated salbutamol in relation to doping analysis

Protection of trial subjects:

Safety of the trial subjects was high prioritized. All procedures are well tolerated. The study was performed under the GCP-guidelines. Standard doses of salbutamol were not exceeded.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2017
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

LFU + doctor examination , VO2max

Period 1

Period 1 title	Salbutamol inhalation
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	inhalation
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Arm description:

400 mcg x 2, 7 days

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

Dosage and administration details:

400 mcg x 2

Number of subjects in period 1	inhalation
Started	20
Completed	20

Period 2

Period 2 title	Salbutamol oral
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	oral
Arm description: 4 mg x 2, 7 days	
Arm type	Experimental
Investigational medicinal product name	Ventoline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

4 mg x 2, 7 days

Number of subjects in period 2	oral
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Salbutamol inhalation
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Reporting group description: -

Reporting group values	Salbutamol inhalation	Total	
Number of subjects	20	20	
Age categorical 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)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	10	10	
Male	10	10	

End points

End points reporting groups

Reporting group title	inhalation
Reporting group description:	
400 mcg x 2, 7 days	
Reporting group title	oral
Reporting group description:	
4 mg x 2, 7 days	

Primary: Urine concentration

End point title	Urine concentration
End point description:	
End point type	Primary
End point timeframe:	
1 week	

End point values	inhalation	oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: ng/ml				
median (full range (min-max))	143 (0 to 2501)	1116 (6 to 6980)		

Statistical analyses

Statistical analysis title	Urine concentration
Comparison groups	inhalation v oral
Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	other
P-value	≤ 0.05
Method	ANOVA

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Intervention + 1-week follow-up after the last dose

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22
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Reporting groups

Reporting group title	Salbutamol oral
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Reporting group description:

20 subjects (10 men and 10 women). Cross-over. Salbutamol was administrated twice a day for one week 4 mg oral salbutamol twice daily or 400 µg inhaled salbutamol twice daily.

Reporting group title	Salbutamol inhalation
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Reporting group description:

20 subjects (10 men and 10 women). Cross-over. Salbutamol was administrated twice a day for one week 4 mg oral salbutamol twice daily or 400 µg inhaled salbutamol twice daily.

Serious adverse events	Salbutamol oral	Salbutamol inhalation	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Salbutamol oral	Salbutamol inhalation	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
Musculoskeletal and connective tissue disorders			
Tremor	Additional description: skeletal muscle tremor related to the administration of both inhaled and oral salbutamol is a well-known side effect of salbutamol		
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
occurrences (all)	2	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