Clinical trial results:
Pharmacological properties of in haled and oral terbutalin administrated in healthy trained males

Summary

EudraCT number	2014-002140-40
Trial protocol	DK
Global end of trial date	01 October 2015

Results information

Result version number	v1 (current)
This version publication date	18 March 2020
First version publication date	18 March 2020

Trial information

Trial identification

Sponsor protocol code	WADA2013ter

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bispebjerg University Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen, Denmark, 2400
Public contact	Respiratory Research Unit, Bispebjerg University Hospital, mhostrup@nexs.ku.dk
Scientific contact	Respiratory Research Unit, Bispebjerg University Hospital, mhostrup@nexs.ku.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	01 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2015
Global end of trial reached?	Yes
Global end of trial date	01 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determine the pharmacological properties of inhaled and oral terbutalin in healthy trained males

Protection of trial subjects:

Safety of the trial subjects was high prioritized. All procedures are well tolerated and at risk periods, the subjects were under surveillance so that a member of staff could intervene if needed. The study was performed under the GCP-guidelines.

Background therapy:

None

Evidence for comparator: -

Actual start date of recruitment	01 September 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment took place from 01/10/14 to 01/01/15

Pre-assignment

Screening details:

Doctors examination
incremental test
ECG and pulmonary functioning testing

Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Terbutaline

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Terbutaline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Inhalation powder
Routes of administration	Inhalation use, Oral use

Dosage and administration details:

10 mg tablet
4 mg inhalation, 2 mg inhalation

Arm title	Terbutaline asthma

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Terbutaline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, Tablet
Routes of administration	Inhalation use, Oral use

Dosage and administration details:

10 mg tablet
1 mg inhalation

Number of subjects in period 1	Terbutaline	Terbutaline asthma
Started	14	10
Completed	12	10
Not completed	2	0
Protocol deviation	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Terbutaline
Reporting group description: -	
Reporting group title	Terbutaline asthma
Reporting group description: -	

Reporting group values	Terbutaline	Terbutaline asthma	Total
Number of subjects	14	10	24
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)	14	10	24
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
median	27	27	
standard deviation	± 2	± 3	-
Gender categorical Units: Subjects			
Female	0	0	0
Male	14	10	24

End points

End points reporting groups	
Reporting group title	Terbutaline
Reporting group description: -	
Reporting group title	Terbutaline asthma
Reporting group description: -	

Primary: Urine Concentrations	
End point title	Urine Concentrations
End point description:	
End point type	Primary
End point timeframe: during the whole study	

End point values	Terbutaline	Terbutaline asthma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	10		
Units: ng/ml				
median (standard error)	1308 (± 269)	17 (± 8)		

Statistical analyses

Statistical analysis title	Urine concentrastion
Comparison groups	Terbutaline v Terbutaline asthma
Number of subjects included in analysis	22
Analysis specification	Post-hoc
Analysis type	other
P-value	≤ 0.05
Method	Shapiro-Wilks

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
During the whole trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	Terbutaline
Reporting group description: -	
Reporting group title	Terbutaline asthma
Reporting group description: -	

Serious adverse events	Terbutaline	Terbutaline asthma	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 10 (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: 1 %

Non-serious adverse events	Terbutaline	Terbutaline asthma	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 14 (28.57%)	2 / 10 (20.00%)	
Cardiac disorders			
Tacchycardia	Additional description: Expected due to side effects		
subjects affected / exposed	2 / 14 (14.29%)	1 / 10 (10.00%)	
occurrences (all)	4	2	
Musculoskeletal and connective tissue disorders			
Tremor	Additional description: Expected due to side effects		
subjects affected / exposed	2 / 14 (14.29%)	1 / 10 (10.00%)	
occurrences (all)	2	1	

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28072631

http://www.ncbi.nlm.nih.gov/pubmed/27375484