Clinical trial results:
Blod and urine concentrations of Procaterol in persons with asthma and elite athletes with asthma: a comparison of inhalation vs. oral administration.

Summary

EudraCT number	2010-023346-78
Trial protocol	DK
Global end of trial date	01 January 2016

Results information

Result version number	v1 (current)
This version publication date	09 February 2017
First version publication date	09 February 2017

Trial information

Trial identification

Sponsor protocol code	PROCAL2010

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 Hospital, mhostrup@nexs.ku.dk
Scientific contact	Respiratory Research Unit, Bispebjerg 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	06 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 January 2016
Global end of trial reached?	Yes
Global end of trial date	01 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the pharmacokinetic and pharmakodynamic properties of inhaled vs oral administered procaterol in healthy young men, asthmatics and elite athletes with astma.

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: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2011
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: 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:

Recruitment started on the 1st of june 2011 and ended on the 15thof december 2012
Recruitment took place in Denmark, mostly in the Greater Copenhagen Area

Pre-assignment

Screening details:

Doctors examination
ECG and pulmonary function testing
Incremental test

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

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	Healthy

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Procaterol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nebuliser solution, Tablet
Routes of administration	Oral use, Not mentioned

Dosage and administration details:

4µg procaterol was administered as nebulization
100µg procaterol was administered orally.

Arm title	Asthmatic

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Procaterol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for nebuliser solution, Tablet
Routes of administration	Not mentioned , Oral use

Dosage and administration details:

4µg procaterol was administered as nebulization
100µg procaterol was administered orally.

Number of subjects in period 1	Healthy	Asthmatic
Started	10	10
Completed	10	10

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Healthy
Reporting group description: -	
Reporting group title	Asthmatic
Reporting group description: -	

Primary: Urine concentrations	
End point title	Urine concentrations
End point description:	
End point type	Primary
End point timeframe:	
During whole trial	

End point values	Healthy	Asthmatic		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: ng/ml				
median (standard error)	47 (± 12)	28 (± 9)		

Statistical analyses

Statistical analysis title	Repeated-measures analysis
Comparison groups	Healthy v Asthmatic
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	1-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From inclusion until 1 week post end of trial

Assessment type	Systematic

Dictionary used

Dictionary name	National Authority
Dictionary version	1

Reporting groups

Reporting group title	Procaterol

Reporting group description: -

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

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Procaterol		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (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 adverse events have been reported.

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/26990656