



Clinical trial results: Small Particle Inhaled Steroids in Refractory Steroid-responsive Asthma Summary

EudraCT number	2010-018249-78
Trial protocol	GB
Global end of trial date	23 October 2013

Results information

Result version number	v1 (current)
This version publication date	14 February 2019
First version publication date	14 February 2019
Summary attachment (see zip file)	A randomised controlled trial of small particle inhaled steroids in refractory eosinophilic asthma (SPIRA) (Spira_pub.pdf)

Trial information

Trial identification

Sponsor protocol code	09115
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01171365
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Nottingham
Sponsor organisation address	Jubilee Campus, Nottingham, United Kingdom, NG51PB
Public contact	Tim Harrison, University of Nottingham, 44 1158231714, tim.harrison@nottingham.ac.uk
Scientific contact	Tim Harrison, University of Nottingham, 44 8231714, tim.harrison@nottingham.ac.uk

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	07 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 October 2013
Global end of trial reached?	Yes
Global end of trial date	23 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In patients with poorly controlled asthma with evidence of persistent eosinophilic inflammation can the addition of extra inhaled corticosteroid that targets the distal airways improve asthma control and reduce the eosinophilic airway inflammation?

The primary endpoint will be the difference in sputum eosinophil count between active and placebo groups at 8 weeks.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2010
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	United Kingdom: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects with poorly controlled eosinophilic asthma

Pre-assignment

Screening details:

ATS criteria for severe asthma

Period 1

Period 1 title	baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	active

Arm description:

ciclesonide

Arm type	Experimental
Investigational medicinal product name	ciclesonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Auricular use

Dosage and administration details:

640 mcg/day

Arm title	placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Auricular use

Dosage and administration details:

as active

Number of subjects in period 1	active	placebo
Started	15	15
Completed	15	15

Baseline characteristics

Reporting groups

Reporting group title	active
Reporting group description: ciclesonide	
Reporting group title	placebo
Reporting group description: -	

Reporting group values	active	placebo	Total
Number of subjects	15	15	30
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)	0	15	15
From 65-84 years	15	0	15
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	7	7	14
Male	8	8	16

Subject analysis sets

Subject analysis set title	Active
Subject analysis set type	Intention-to-treat
Subject analysis set description: To compare high dose ciclesonide with placebo	
Subject analysis set title	placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: placebo control	

Reporting group values	Active	placebo	
Number of subjects	15	15	
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)	15	15	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	8	8	

End points

End points reporting groups

Reporting group title	active
Reporting group description: ciclesonide	
Reporting group title	placebo
Reporting group description: -	
Subject analysis set title	Active
Subject analysis set type	Intention-to-treat
Subject analysis set description: To compare high dose ciclesonide with placebo	
Subject analysis set title	placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: placebo control	

Primary: sputum eosinophils

End point title	sputum eosinophils
End point description:	
End point type	Primary
End point timeframe: week 8	

End point values	active	placebo	Active	placebo
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	15	15	15	15
Units: percent	15	15	15	15

Statistical analyses

Statistical analysis title	sputum cell counts
Comparison groups	placebo v Active
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Median difference (final values)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

duration of study

Assessment type	Non-systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	1
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Reporting groups

Reporting group title	active
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Reporting group description: -

Reporting group title	placebo
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Reporting group description: -

Serious adverse events	active	placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (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: 3 %

Non-serious adverse events	active	placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	3 / 15 (20.00%)	
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 15 (0.00%)	3 / 15 (20.00%)	
occurrences (all)	0	3	

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.

proxy measures of exacerbations

Notes: