Clinical trial results:
The pharmacokinetics and anti-inflammatory effects of prednisolone in severe asthma.

Summary

EudraCT number	2007-002084-27
Trial protocol	GB
Global end of trial date	12 November 2013

Results information

Result version number	v1 (current)
This version publication date	02 January 2020
First version publication date	02 January 2020
Summary attachment (see zip file)	Study ended prematurely (2007-002084-27 EOT notification form_13Nov2013.pdf)

Trial information

Trial identification

Sponsor protocol code	cro-725

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Fan Chung, Imperial College London, f.chung@imperial.ac.uk
Scientific contact	Fan Chung, Imperial College London, f.chung@imperial.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	12 November 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 November 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study is to establish why severe asthmatic patients do not respond to oral corticosteroids as do non-severe asthmatics - is it due to abnormal/subtherapeutic levels or inability to exert its anti-inflammatory effects?
Aims and objectives
1. To evaluate blood prednisolone levels and their anti-inflammatory effects in two severe asthma groups, comparing patients on inhaled corticosteroids (ICS) alone to those on ICS plus oral prednisolone, and a group of well-controlled moderately severe asthmatics.
2. To evaluate if a 14-day course of prednisolone affects 'spot'(one-off) measurements of prednisolone levels, and if these are influenced by taking regular prednisolone
3. To determine the relationship between blood levels of prednisolone and its anti-inflammatory effects
Primary endpoints:
1. serum prednisolone levels over 24 hours
2. change in FEV1 24 hours post prednisolone
3. changes in eNO, sputum eosinophils and inflammatory mediators over 24 hours

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 November 2013
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial ended prematurely. See end of study notification for details. Staffing shortages and recruitment issues. 99999 is "Not applicable" value or 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Prednisolone

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

8 x 5mg = 40 mg

Number of subjects in period 1	Prednisolone
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial (overall period)

Reporting group description: -

Reporting group values	Overall Trial (overall period)	Total	
Number of subjects	99999	99999	
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Prednisolone

Reporting group description: -

Primary: evaluate blood prednisolone levels

End point title	evaluate blood prednisolone levels[1]

End point description:

End point type	Primary

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: The study ended prematurely.

End point values	Prednisolone			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: 8 x 5mg = 40 mg	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the trial were to be collected.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

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

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: The study ended prematurely.

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.

99999 is "Not applicale" value or 0 participants. The trial ended prematurely.

Notes: