



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: