



Clinical trial results:

Targeting systemic inflammation to improve endothelial function in obesity

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2009-016855-23 |
| Trial protocol | GB |
| Global end of trial date | 05 August 2013 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 26 July 2020 |
| First version publication date | 26 July 2020 |
| Summary attachment (see zip file) | Obesity in ECF letter (Obesity in ECF letter.docx) |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | CD09/9088 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | University of Leeds |
| Sponsor organisation address | Worsley Building, Leeds, United Kingdom, LS2 9JT |
| Public contact | Prof Stephen Wheatcroft, University of Leeds, S.B.Wheatcroft@leeds.ac.uk |
| Scientific contact | Prof Stephen Wheatcroft, University of Leeds, S.B.Wheatcroft@leeds.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 | 05 August 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 05 August 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 August 2013 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

Does reducing inflammation in obese volunteers, using pentoxifylline, lead to an improvement in the health of blood vessels?

We will measure the health of blood vessels by taking blood samples and carrying out an ultrasound scan of the blood vessel in the arm before and after treatment.

This will address whether inflammation causes 'unhealthy' blood vessels in people with obesity.

Protection of trial subjects:

The IMP has been investigated in several published trials in a range of medical conditions. These include trials of efficacy in chronic obstructive pulmonary disease, alcoholic hepatitis, contrast-induced nephropathy, haemodialysis-related anaemia, proteinuria, breast fibrosis and endothelial activation. No new significant adverse effects of the IMP were identified during the trial. All research team members undertook GCP training, and the trial was interdependently monitored by the sponsor.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 10 January 2011 |
| 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:

Potential study participants will initially be recruited from obesity/obesity surgery clinics held within Leeds Teaching Hospitals NHS Trust. Potential participants will be approached directly by members of staff (recorded on the study delegation log) at their clinic appointment.

Pre-assignment

Screening details:

A verbal explanation of the trial and Participant Information Sheet will be provided by the authorised trial clinician or research nurse for the individual to consider. Assenting patients will then be formally assessed for eligibility and invited to provide informed, written consent.

Period 1

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

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Intervention |

Arm description: -

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

Dosage and administration details:

The IMP or placebo will be supplied to participants in a bottle to be taken three times daily for eight weeks. This provides 400mg of pentoxifylline three times daily for 8 weeks

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description: -

| | |
|--|------------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo identical size 00 capsules |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo capsules will comprise identical size 00 capsules (containing talc only).

| Number of subjects in period 1 | Intervention | Placebo |
|---------------------------------------|--------------|---------|
| Started | 1 | 99998 |
| Completed | 1 | 99998 |

Baseline characteristics

End points

End points reporting groups

| | |
|--------------------------------|--------------|
| Reporting group title | Intervention |
| Reporting group description: - | |
| Reporting group title | Placebo |
| Reporting group description: - | |

Primary: Number of Patients with Flow-mediated dilatation of the brachial artery

| | |
|------------------------|--|
| End point title | Number of Patients with Flow-mediated dilatation of the brachial artery ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| measured at week 8 | |

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: A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA it was agreed that the trial teams would not pursue publication for this trial and results analysis was halted. It was agreed with the MHRA in September 2019 that a full data upload on EudraCT is not required.

| End point values | Intervention | Placebo | | |
|-----------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | | |
| Units: patients | | | | |

Notes:

[2] - data analysis is incomplete for this trial.

[3] - data analysis is incomplete for this trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

AEs will be collected for all patients and will be evaluated for duration and intensity according to the NCRI Common Toxicity Criteria.

Adverse event reporting additional description:

AEs will be collected for all patients from first dose of protocol treatment until 30 days after the last dose of treatment with a protocol IMP.

Information about AEs, whether volunteered by the patient, discovered by the investigator questioning or detected through physical examination, laboratory test or other investigation will be collected

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|-------|
| Dictionary name | CTCAE |
| Dictionary version | 4 |

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: A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA it was agreed that the trial teams would not pursue publication for this trial and results analysis was halted.

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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