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:

he 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 its 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 its 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