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Targeting systemic inflammation to improve endothelial function in obesity

Submission date	Recruitment status	[_] Prospectively registered
10/06/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2022	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen B Wheatcroft

Contact details
The Light Laboratories
University of Leeds
Clarendon Way
Leeds
United Kingdom
LS2 9DA
+44 113 343 7760
s.b.wheatcroft@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
2009-016855-23

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9379

Study information

Scientific Title
Targeting systemic inflammation to improve endothelial function in obesity

Study objectives
The aim of this study is to investigate the effect of reducing inflammation with pentoxifylline on vascular endothelial function in individuals with obesity

Ethics approval required
Old ethics approval format

Ethics approval(s)
02/02/2010, ref: 10/H1005/5

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
A total of 50 participants with obesity will be randomised to receive pentoxifylline 400mg tablets or an inactive control preparation three times daily for eight weeks.
Follow Up Length: 2 month(s); Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pentoxifylline

Primary outcome measure
Flow mediated dilatation of brachial artery (%); Timepoint(s): at end of treatment period

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2010

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Age 18-65
2. Obesity (Body Mass Index 30 or greater)
3. Not taking other medication (apart from oral contraceptives)
Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Diabetes
2. Hypertension
3. Hyperlipidaemia
4. Cardiovascular disease or history of cardiac arrythmias
5. Chronic inflammatory disorders (e.g. rheumatoid arthritis, connective tissue disorders, gout, inflammatory bowel
disease, chronic infections)
6. Acute inflammatory illnesses (e.g. upper respiratory tract infections)
7. Allergy to pentoxifylline or other methyl xanthine drugs or concomitant use of sildenafil, tadalafil, vardenafil or other phosphodiesterase inhibitors
8. History of cerebral haemorrhage or retinal haemorrhage

9. Pregnancy or breastfeeding
10. Impaired renal function

Date of first enrolment
01/12/2010

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Light Laboratories
Leeds
United Kingdom
LS2 9DA

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
The Light Laboratories
University of Leeds
Clarendon Way
Leeds
England
United Kingdom
LS2 9DA

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/07/2020	19/05/2022	No	No
HRA research summary			28/06/2023	No	No