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Vascular function in obesity

Submission date 15/04/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/04/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/07/2020	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a term used to describe somebody who is very overweight, with a lot of body fat. It's a common problem, estimated to affect around one in every four adults and around one in every five children aged 10 to 11 in the UK. People who are obese are at risk of a number of serious and potentially life-threatening conditions, such as high blood pressure. High blood pressure is dangerous because it can have no symptoms, and increases the risk of a heart attack or stroke. It can also cause permanent damage to vital organs, such as the kidney, eye, brain and heart. Normally, high blood pressure can be treated with medications but these medications don’t work very well in obese patients and we’re not sure why. Most information on blood vessel structure comes from blood vessels studied in a laboratory. Here, we are using a technique which allows us to view blood vessels in the patient directly. Eye (retinal) blood vessel analysis is a non-invasive way to measure the structure of small blood vessels in a patient. The aim of this study is to get a better understanding of the differences in small blood vessel structure between obese patients and lean patients.

Who can participate?
Adults with a BMI over 30 or lower than 25.

What does the study involve?
Participants have non-invasive tests to check how well their blood vessels are functioning. Two of these tests are eye tests. There is also a blood test.

What are the possible benefits and risks of participating?
There are no risks or benefits to participating in this study.

Where is the study run from?
Wellcome Trust Clinical Trials Facility, Central Manchester University Hospitals Trust (UK)

When is the study starting and how long is it expected to run for?
June 2015 to January 2017

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr A Greenstein (scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1; 13/4/14

Study information

Scientific Title
Identification of cardiovascular changes in obesity using dynamic and static retinal vessel analysis

Study objectives
Changes in retinal vessel function can be correlated with obesity, blood pressure, pulse wave velocity and blood metabolic markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester South Research Ethics Committee, 29/07/2015 ref: 15/NW /0548

Study design

Single site cohort observation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cardiovascular disease associated with obesity

Interventions
All participants who express an interest in study participation will be invited to attend Manchester Clinical Research Facility. Following informed consent procedure (estimated to take approximately 15mins), all participants will undergo:
1. Assessment of past medical history and physical examination: height, weight, waist circumference (10 mins)
2. Pupil dilation (Tropicamide eye drops applied taking 2 minutes to perform but up to 20 minutes to take effect)
3. Blood sampling – up to 10ml (2 teaspoon blood) takes up to 10mins to perform
4. Pulse Wave velocity measurement lay in supine position (10 mins)
5. Blood pressure will be recorded at the start and end of procedure but also throughout the assessment using a wrist cuff
6. Dynamic retinal vessel analysis (flicker stimulation) (15 mins)
7. Static retinal vessel analysis (10 mins)
8. Oxygen saturation will be measured by taking a photograph of the fundus of the eye (5 mins)
9. Carbon dioxide inhalation – during the imaging examination of the eye, a mixture of 95% air /5% carbon dioxide will be administered via nasal cannula (procedure takes 2-3 minutes but gas will be administered for only 45 seconds)
10. On completion of the assessment, participants will be given the general advice leaflet for Tropicamide and advised not to drive for 4 hours This completes study participation.
Total duration of assessment not expected to be more than 2 hours.

Intervention Type
Other

Primary outcome measure
Vascular function measured by degree of response to flicker stimulation, retinal arteriolar-venular ratio (AVR) and blood oxygen saturation on the assessment day.

Secondary outcome measures

Peripheral measurements: blood pressure, pulse wave velocity and blood levels of HbA1c and blood lipids (triglycerides, LDL and HDL cholesterol) on the assessment day.

Overall study start date
01/02/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Patient-participants:
1. Willing and capable to provide consent to participation
2. BMI greater than 30
3. No known ocular diseases
4. No known concurrent clinical problem likely to interfere with participation or completion of the study

Healthy controls:
1. BMI lower that 25
2. No known diabetes
3. No known ocular diseases
4. No known concurrent clinical problem likely to interfere with participation or completion of the study

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
30 healthy lean controls and 30 obese patient-participants

Key exclusion criteria
1. Under 18 years old
2. Intubated/ventilated patients
3. Unwilling to give consent to participation OR advised by consultee that this would be against the patient’s wishes
4. Smoker
5. If eaten with in an hour of the examination
6. If drank alcohol within an hour of the examination
7. If drank coffee within an hour of the examination
8. If overly hungry
9. Recently treated infection
10. Known ocular diseases

11. Known concurrent clinical problem likely to interfere with participation or completion of the study

Additional exclusion for healthy controls:
1. Diabetes
2. BMI above 25

Date of first enrolment
01/06/2015

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Clinical Research Facility
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
The University of Manchester

Sponsor details
Oxford Road
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Sponsor type
University/education

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from adam.greenstein@manchester.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No