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Measuring blood vessel function using diffuse optical tomography

Submission date	**Recruitment status**	[X] Prospectively registered
20/07/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/08/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2015	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atherosclerosis is a serious disease where fatty substances, called plaques, build up in the arteries. The plaques can cause hardening and narrowing of the arteries, which leads to reduced flow of blood through the blood vessels. Factors which increase the risk of a person developing atherosclerosis, such as smoking, as well as conditions such as diabetes, are also thought to increase a persons' risk of developing microvascular disease (MVD). MVD is a disease where the small arteries in the heart become narrowed because of plaque. Therefore when the body's demand for oxygen is increased by stress or exercise, the vessels can't expand to increase the blood supply to the coronary arteries, which can lead to a heart attack. The usual test plaque in the arteries of the heart is coronary angiography, which uses a dye and special x-rays to show how blood is moving through the coronary arteries. The aim of this study is to find out whether using a technique called diffuse optical tomography (DOT), which painlessly shines light into the arm and measures the reflections, would be able to more accurately assess microvascular function than existing tests.

Who can participate?
Adult suffering from diabetes, or who have had a heart attack, or who are awaiting coronary angiography

What does the study involve?
All participants undergo DOT, which involves having near-infrared light shone through their arm in order to test how well the blood is flowing in the main artery in the upper arm (brachial artery). This will show if the blood flow is restricted in any way due to plaque build-up. For the participants who are having a coronary angiogram, the results of this are compared to the results of the DOT test, to see if there is a link.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2015 to July 2018

Who is funding the study?
University of Sheffield (UK)

Who is the main contact?
Dr Timothy Chico
t.j.chico@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Timothy Chico

Contact details
Department of Cardiovascular Science
University of Sheffield
Medical School
Beech Hill Road
Sheffield
United Kingdom
S10 2RX
+44 (0)114 222 2396
t.j.chico@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STH18992

Study information

Scientific Title
Quantitative assessment and characterization of microvascular function using diffuse optical tomography

Study objectives
We hypothesise that diffuse optical tomography can detect differences in vascular function between healthy participants and people with diabetes or previous heart attack, or between people with and without coronary artery disease on angiography.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Observational

Primary study design
Observational

Secondary study design
Pilot feasibility trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease and diabetes

Interventions
Measurement of vascular function in the forearm by diffuse optical tomography during reactive hyperaemia response after brachial artery occlusion

Intervention Type
Device

Primary outcome measure
Vascular function parameters measured by diffuse optical tomography after 5min brachial artery occlusion

Secondary outcome measures
Feasibility and reproducibility of vascular function measurement by diffuse optical tomography

Overall study start date
01/08/2015

Completion date
31/07/2018

Eligibility

Key inclusion criteria
Healthy volunteers
1. Aged between 18-80 years
2. Ability to read and speak English to a level allowing understanding of the patient information and to give consent to participate

Diabetics:
1. Aged between 18-80 years
2. Ability to read and speak English to a level allowing understanding of the patient information and to give consent to participate
3. Diagnosed as type 1 or 2 diabetic for at least 12 months

Prior myocardial infarction:
1. Aged between 18-80 years
2. Ability to read and speak English to a level allowing understanding of the patient information and to give consent to participate
3. Suffered a myocardial infarction at least 1 month previously

Patients awaiting coronary angiography:
1. Aged between 18-80 years
2. Ability to read and speak English to a level allowing understanding of the patient information and to give consent to participate
3. Awaiting an invasive or CT coronary angiogram for clinical reasons

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
Healthy volunteers:
1. No history of diabetes, myocardial infarction, or major cardiovascular disease
2. No painful arms or health problems preventing blood pressure cuff inflation
3. No lymphoedema of the arm

Diabetics:
1. No painful arms or health problems preventing blood pressure cuff inflation
2. No lymphoedema of the arm

Prior myocardial infarction:
4. No painful arms or health problems preventing blood pressure cuff inflation
5. No lymphoedema of the arm

Patients awaiting coronary angiography:
1. No painful arms or health problems preventing blood pressure cuff inflation
2. No lymphoedema of the arm
3. Not diabetic or known to have suffered a myocardial infarction in the past

Date of first enrolment
01/09/2015

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S10 2TN

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
D Floor, Royal Hallamashire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2TN
+44 (0)114 271 2763
nana.theodorou@sth.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Results and Publications

Publication and dissemination plan
We will present our findings at national and international conferences, and submit manuscripts to peer-reviewed journals, with preference to those which deposit publications in open access databases to increase free dissemination. Lay summaries of the research will be provided to the media office for press release. Once the findings are published in a peer-reviewed journal, a lay summary will be sent to participants by post.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available