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Measuring blood vessel function using diffuse optical tomography

Submission date
20/07/2015

Recruitment status
No longer recruiting

Registration date
20/08/2015

Overall study status
Completed

Last Edited
20/08/2015

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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.

Primary study design
Observational

Study design
Observational

Study type(s)
Diagnostic

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(s)
Vascular function parameters measured by diffuse optical tomography after 5min brachial artery occlusion

Key secondary outcome(s)
Feasibility and reproducibility of vascular function measurement by diffuse optical tomography

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available