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Non-invasive assessment of cardiovascular risk

Submission date 02/09/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/09/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/09/2013	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD) covers a number of heart and circulatory diseases including heart attack, stroke, coronary artery disease and heart failure. In the UK it is the cause of a quarter of all deaths and is thought to cost the economy around £19 billion a year. CVD has a long phase where the disease is present but the sufferer does not show symptoms. There is a need to develop a test where CVD and people at risk of developing the disease can be identified as early as possible so that they can receive the care they need. This study aims to test a new, simple, low-cost medical device which has been developed to assess a persons risk of CVD. The device shines a light on the patients arm to see if the blood vessels are responding the way they should to a period of decreased blood flow or if they are showing signs of disease. The study will test how reliable this new device is and if it is able to spot patients who have CVD or who may go on to develop CVD in the future. It will also look at whether the new test is acceptable to patients by asking them for feedback about their experience.

Who can participate?
The study involves male and female participants who are 18-80 years old and attending hospital for tests relating to CVD.

What does the study involve?
Participants complete one study visit where one measurement will be taken with the new device and questions asked about the participants medical history, demographics and their experience of the test. Participants who agree to follow up will then be followed for 10 years by the research team who will access their medical records and record results of any tests relating to CVD.

What are the possible benefits and risks of participating?
There is no direct benefit to participants taking part in the study; however, this research may lead to the development of a new test which could help others in the future. The risks involved in taking part in the study are very small and similar to that of getting your blood pressure taken.

Where is the study run from?
The study will be run at one site in Ninewells Hospital, Dundee, Scotland (UK).

When is the study starting and how long is it expected to run for?
Recruitment will begin around March 2014 and 200 study visits will be completed over a period of 4 months. There will then be a 10 year follow up period.

Who is funding the study?
The study is funded by Northwood Trust and Scottish Enterprise, UK.

Who is the main contact?
Professor C. Jackson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
SEPOC1

Study information

Scientific Title
Assessing the use of light as a non-invasive tool for the evaluation of individual risk of cardiovascular disease

Study objectives
Is a new test using light a reliable indicator of an individual's risk of developing cardiovascular disease?

Primary objective
To verify that the investigational device works as proposed by the manufacturer in a clinical setting.

Secondary Objectives
1. To determine the correlation between measurements made using photonics after induced ischaemia on a patients forearm and other currently used diagnostic evaluations of CVD.

2. To determine which of the above, independently, most strongly predicts exacerbation rates retrospectively (current diagnostic evaluations or photonics device).
3. To determine the acceptability of the photonic measurement as a potential screening tool for CVD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ref: 13/SS/0172. The study will be reviewed by South East Scotland REC 2 on 25th September 2013.

Primary study design
Interventional

Study design
Single site medical device feasibility study

Study type(s)
Diagnostic

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

Interventions
Participants will undergo one test with the new device. This consists of having an inflatable blood pressure cuff placed on the upper arm and a low intensity light source shone on the lower arm. The test takes around 10mins to compete in total. Participants will then be asked questions regarding their experience of the new test.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The reliability of the device as measured by number of decipherable measurements produced during the study.

Key secondary outcome(s)
1. Correlation between device measurement and current diagnostic results
2. Correlation between follow up exacerbation rate and device measurement
3. Acceptability of device measurements as described by participant feedback scores and number of adverse device effects recorded

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Written informed consent given by participant.
2. Male or female patients aged 18 to 80 years inclusive.
3. Undergoing investigations for cardiovascular disease (CVD)
4. Is likely to have, or has had recent diagnostic investigations performed as part of routine clinical care relevant to diagnosis of CVD

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
1. Any clinically significant medical condition or abnormality, which, in the opinion of the investigator, or cardiologist might compromise the safety of the patient
2. Females who are known to be pregnant or lactating

Date of first enrolment
01/03/2014

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
School of Medicine
St Andrews
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KY16 9TF

Sponsor information

Organisation
University of St Andrews (UK)

ROR
https://ror.org/02wn5qz54

Funder(s)

Funder type
Industry

Funder Name
Northwood Trust (SC013532) (UK) - ref: F611XX

Funder Name
Scottish Enterprise (Uk) - ref: PS7305CA20

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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