ISRCTN13301188 https://doi.org/10.1186/ISRCTN13301188

Novel pulse device for diagnosis of peripheral arterial disease (NOTEPAD)

Submission date
23/09/2015

Recruitment status
No longer recruiting

Registration date
13/10/2016

Overall study status
Completed

Last Edited
24/10/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Peripheral arterial disease (PAD) is a common condition in which the blood flow to the legs is restricted. This happens because of the buildup of a fatty substance (plaque) and calcium salts on walls of arteries, which becomes hardened (calcification) leading to reduced flow of blood through the blood vessels. Over time this can cause the main arteries in the legs to become narrowed (stenosed). This can cause a severe cramping pain in the legs when exercising (claudication), as the restricted blood flow cannot deliver enough oxygen to the leg muscles. Eventually, the arteries can become completely blocked, cutting off the blood supply and leading to ulcers and gangrene, which can result in amputation. Detecting PAD early allows its risk factors to be controlled but currently there are no devices which general practitioners can easily use to diagnose PAD. The Ankle Brachial Pressure Index (ABPI) test has been recommended but is time consuming and few healthcare professionals have been properly trained in the technique. The test works by comparing the pressure of blood in the arteries in the arms and legs – if the measurement in the leg is lower than the arm then this means that the arteries are likely to be blocked. This study will test a newly developed PAD detector device called MPPG which is comfortable for patients and easy to use in any clinical setting. Initial studies have indicated that it substantially agrees with the currently recommended ABPI assessments. The aim of this study is to evaluate that the MPPG is as good if not better than ABPI in a GP clinic setting.

Who can participate?
Adult patients with PAD and healthy adults without PAD.

What does the study involve?
All participants attend an appointment at their local GP practice. At the appointment, the ABPI is undertaken. This involves having a blood pressure cuff inflated around the calf and slowly deflated as a small ultrasound probe is used to detect the pulse from two places on the foot. These values are then used, along with blood pressure measurements taken from the arms, to calculate the ABPI. Next, participants undergo the MPPG test. This involves small blood flow sensor clips being gently attached to specific peripheral sites and the pulses measured for analysis. Patients finally undergo a duplex ultrasound scan of both legs, whiwhich shows up significant blockages. Duplex ultrasound is currently the best way of measuring whether arteries

are blocked (a gold or index standard). The ability of the ABPI test and MPPG test for diagnosing PAD is then compared to the results of the ultrasound scan.

What are the possible benefits and risks of participating?
There is no direct benefit to participants in this trial. However, findings in this study will contribute to further understanding of this disease and potentially lead to earlier diagnosis of PAD in the future. There are no notable risks involved with participating in this study.

Where is the study run from?
Royal Victoria Infirmary (UK)

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Michael White
Michael.white@nuth.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Michael White

Contact details
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18101

Study information

Scientific Title
Innovative photoplethysmography technology for rapid non-invasive assessment of peripheral arterial disease in primary care (NOTEPAD)

Acronym
NOTEPAD

Study objectives
The aim of the study is to evaluate the performance of innovative MPPG photoplethysmography technology when diagnosing peripheral arterial disease (PAD) in comparison to ankle brachial pressure index (ABPI) when used in a GP setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 1 Research Ethics Committee, 13/01/2015, ref: 14/NE/1238

Study design
Observational case-control diagnostic accuracy study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Treatment

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
Peripheral arterial disease (PAD)

Interventions
GP Practices will identify eligible patients and send invite letters in the post. Once an invite is accepted, the GP Practice will match the PAD patient with a control (matched by age and sex) and send out another invitation. At this stage, the NOTEPAD team and GP Practice will work collaboratively to arrange a clinic. When a patient attends this clinic, they will first be consented and then be asked to do a short questionnaire. They will then be invited for ABPI and MPPG measurements (order is randomized). These procedures will take approximately 45 minutes. A Duplex ultrasound scan of the legs will then be performed to provide a reference standard for PAD, this will take a further 45 minutes.

Once these three measurements are complete the patient will be free to leave and no follow ups are required.

ABPI (current recommended standard test): A portable Doppler ultrasound probe is used to measure the systolic blood pressures in the posterior tibial and dorsalis pedis arteries for each foot, with the probe detecting the return of the pulse at each site during careful ankle blood pressure cuff deflation. The brachial systolic pressures for the right and left arms are measured the same way and then the ABPI is calculated (with normal range between 0.9 and 1.3).

MPPG (index test): Small optical sensor clips are gently attached to specific finger, toe and ear sites to detect the blood flow pulses.

Duplex ultrasound scan (reference standard test): Participants will have a duplex ultrasound scan performed on both legs by a vascular scientist.

Intervention Type
Other

Primary outcome measure
Diagnostic accuracy of MPPG and ABPI with each compared with Duplex scan using values of sensitivity, specificity, and positive and negative predictive values.

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/02/2015

Completion date
31/01/2017

Eligibility

Key inclusion criteria
Patients:
1. Aged 45 years and over
2. Provision of informed consent
3. Diagnosed with PAD

Controls:
1. Aged 45 years and over
2. Provision of informed consent
3. Not diagnosed with PAD

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Those under 45 years of age
2. Those unable to provide informed consent.
3. Individuals with renal failure receiving renal support therapy (ESRF)
4. Patients with tender or painful calves, ankles or feet who would be unable to tolerate ABPI measurements (ulcerated legs)
5. Toe/limb amputees (bilateral comparisons needed to make pulse and pressure-based assessments)
6. PPG measurement site (big toe pad, index finger pad, earlobe) having any visible damage to local skin area (skin needs to be intact)
7. Significant limb tremor
8. Patients unable to understand English sufficiently to give informed consent

Date of first enrolment
13/05/2015

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Leazes Wing
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Northern Medical Physics and Clinical Engineering
Freeman Hospital
Freeman Road
Newcastle upon Tyne
England
United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/services/medical-physics.aspx

ROR
https://ror.org/05p40t847

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
Study results will be shared widely and in particular will be disseminated to GP Practices, Vascular Surgical Groups and vascular disease charities. It is also planned to publish articles and present the findings of this research to scientific conferences. It is envisaged that findings will be disseminated through the media.

Intention to publish date
31/12/2017

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?
Interim results article	substudy results	01/01/2020	23/09/2020	Yes	No
Interim results article		05/01/2021	24/10/2022	Yes	No
Interim results article		06/09/2019	24/10/2022	Yes	No
Interim results article		16/05/2019	24/10/2022	Yes	No
Interim results article		17/09/2018	24/10/2022	Yes	No
Interim results article	Background paper	01/06/2015	24/10/2022	Yes	No
Interim results article	Qualitative study	01/10/2019	24/10/2022	Yes	No
Interim results article	Qualitative study	07/11/2019	24/10/2022	Yes	No
Interim results article	Signal processing approach	29/01/2018	24/10/2022	Yes	No
Interim results article	Sub study	21/12/2020	24/10/2022	Yes	No
Interim results article	Systematic review	23/04/2018	24/10/2022	Yes	No
Results article	Main results	25/04/2022	24/10/2022	Yes	No
Results article		18/08/2022	24/10/2022	Yes	No
HRA research summary			28/06/2023	No	No