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A novel ultrasound method for heart failure detection

Submission date	Recruitment status	[ ] Prospectively registered
23/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/07/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
When the heart contracts with each heartbeat, the heart generates a wave of increased pressure and flow of blood, which also leads to an increased diameter of the artery. This wave travels down our arteries. Heart failure is a condition where the heart does not contract adequately, and the characteristics of the waves generated are therefore altered. Therefore, in theory, these waves can help us diagnose heart failure.
However, current methods for measuring waves travelling in our arteries are too invasive, cumbersome, inaccurate or expensive for everyday use. Therefore, we have developed a method using simple ultrasound that may overcome these problems. We have already demonstrated that this method works for detecting heart failure in rabbits. We now wish to test the potential of the method in people. We will be assessing the precision and accuracy of the method, and whether it can distinguish between patients with heart failure and patients without heart failure. At present, diagnosis of heart failure is costly and time consuming, requiring echocardiography with expert clinical assessment. Our new method could be installed on existing clinical ultrasound scanners and used by non-specialists for screening, tracking responses to drugs and providing diagnostic information that cannot be obtained by echocardiography.

Who can participate?
Adults who are undergoing routine clinical transthoracic echocardiography and who are able to give informed consent can participate in this clinical trial.
For control groups, people with known arrhythmias, hypertension (except for the hypertensive control group), hyperlipidemia, aneurysm, diabetes, heart failure, or taking medication for cardiovascular conditions will not be invited to participate. Those who lack the capacity to consent will not be invited to participate.

What does the study involve?
The study involves a series of ultrasound measurements taken at the neck, at the upper arm and at the wrist over no more than thirty minutes. Patients will also undergo ECG monitoring, and blood pressure recordings will also be taken at the upper arm. All measurements will be taken whilst participants are reclining on a medical bed.

What are the possible benefits and risks of participating?
There are potential benefits in being able to participate in clinical research, perhaps particularly so for people with heart failure, which is a largely chronic and unremitting disease.
There is a potential that clinically significant disease such as carotid artery stenosis may be suggested by the ultrasound scans. If this possibility is raised then the participants will be informed and the research team will communicate with the participant's clinical team (for example the participant's GP). This possibility is described in the participant information sheet.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2019 to August 2024

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

Who is the main contact?
Dr Anenta Ramakrishnan, ar203@ic.ac.uk
Prof. Peter Weinberg, p.weinberg@imperial.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
248724

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 248724, CPMS 40078

Study information

Scientific Title
Arterial pulse waves in heart failure

Acronym
Arteriowave

Study objectives
Our hypothesis is that our novel ultrasound-based methodology for wave intensity analysis can be performed on human participants reliably and with reproducibility, and that wave intenisty will be reduced in participants with heart failure with reduced ejection fraction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2018, South Central - Hampshire B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 1048055; hampshireb.rec@hra.nhs.uk), ref: 18/SC/0563

Study design
Single-centre observational case-control study

Primary study design

Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Heart failure or those with left ventricular diastolic dysfunction but without clinical symptoms or signs of heart failure

Interventions
Measurements are taken on one occasion. Non-invasive ultrasound measurements will be performed on participants with ECG monitoring. Measurements at the radial, brachial and carotid artery will be attempted. Blood pressure recordings from each participant will be recorded using a peripheral brachial arm blood pressure cuff. Subsequently, analysis of ultrasound measurements will be compared to transthoracic echocardiograms that have been previously performed on participants.

Intervention Type
Other

Primary outcome(s)
At a single time point:
1. Wave intensity metrics obtained from non-invasive ultrasound measurements taken from the carotid, brachial and radial arteries using a range of ultrasound scanners (At present, a research ultrafast scanner is used.)
2. Routinely collected transthoracic echocardiography data using patient records.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Healthy volunteers:
1. Members of staff who are clinically well

Patients:
1. Patients with heart failure and left ventricular systolic impairment (ejection fraction, measured by biplane Simpsons methodology on echocardiography, <40%)
2. Patients with heart failure and preserved left ventricular systolic function (ejection fraction >50%)
3. Patients without clinical symptoms or signs of heart failure but with left ventricular diastolic dysfunction with an E/E’ ratio of 15+

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
148

Key exclusion criteria
1. Known arrhythmias
2. Hypertension (except for the hypertensive control group)
3. Hyperlipidemia
4. Aneurysm
5. Diabetes
6. Heart failure
7. Taking medication for cardiovascular conditions
8. Lack capacity to consent

Date of first enrolment
12/11/2019

Date of final enrolment
06/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
Imperial College Healthcare NHS Trust
Cardiovascular Offices, B Block, 2nd Floor
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Access to trial IPD can be requested by qualified researchers engaging in independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). For more information or to submit a request please contact Anenta Ramakrishnan at a.ramakrishnan@nhs.net

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes