ISRCTN13922377 https://doi.org/10.1186/ISRCTN13922377

Cardisio - detection of heart disease in primary care

Submission date
16/06/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
12/11/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
This study is designed to assess how a relatively simple cardiovascular disease (CVD) test procedure can be used in conjunction with existing NHS community-based CVD prevention strategies for earlier detection of CVD. The proposed Cardisio test procedure is new to the UK market and uses sophisticated artificial intelligence (AI)-based algorithms to detect the early signs of heart disease. It is easy to train staff in the use of The Cardisio Test, it is simple to conduct and produces results quickly and accurately. The study objective is to show that the Cardisio Test can be easily integrated into an existing NHS care pathway (NHS Right Care CVD Prevention) in a variety of community & primary care settings. The secondary outcome is to gain real-world evidence of its performance as a tool, to aid clinicians with the early detection of heart disease in community-based settings. Findings from this study will be incorporated into a proposed integrated care system-based national roll-out plan.

Who can participate?
Patients aged 18-75 years old who have a risk of developing CVD

What does the study involve?
The 4-minute test is similar to a conventional Electro-Cardio-Gram (ECG) test except the Cardisio Test only uses five electrodes. The electrodes are placed on the chest and back of the study Participant. They are lightly attached to the skin using a clear gel and the test is started, which records 4 minutes of electrical activity of the heart. Once complete the electrodes are removed. Following the completion of the test, the data collected is automatically transmitted to a central computer, which uses AI to compare the signals of the test to signals previously taken from healthy and unhealthy hearts. This takes 2 or 3 minutes, and the results are sent to a Cardiologist for review.
The Participant will be contacted by the Cardiologist with the results and may decide that further action is required. If so, any further actions will follow the current standard CVD procedures used in NHS primary and secondary care settings.

What are the possible benefits and risks of participating?
Those that volunteer to participate in the study will only be selected if they have a higher risk than average for having CVD. The Cardisio heart test has already been proven to detect the early

stages of some types of CVD. Therefore, the test performed during the study may detect early signs of CVD. This can dramatically improve the chances of avoiding a potentially damaging condition progressing and helps with the earlier identification of treatment required.
There may be a small risk of an allergic skin reaction to the gel used in the ECG-type electrodes. The participants' skin will need to be cleaned with a non-alcohol wipe to ensure good skin contact and conductivity. Some participants may need to have a small skin area shaved to ensure good skin contact, which may have cultural or religious implications. This is explained in the participant leaflet. For female patients who have never had an ECG-type test done, they may not be aware that outer clothing and possibly undergarments may have to be removed, in order to locate the sensors. We have made provisions for chaperones to be in attendance and ensured that testers are multilingual. It is still possible that participants may choose to withdraw from the study at this stage. All sites/personnel are CQC registered and the test areas are private.

Where is the study run from?
Sandwell Hospital in West Midland (UK), with testing sites located in Dudley, Quinton and Aston, all in the Birmingham area (UK)

When is the study starting and how long is it expected to run for?
December 2022 to February 2024

Who is funding the study?
The Study is funded by Nottingham University Hospitals Hospital NHS Trust (UK) through Funding administrators SBRI HealthCare Ltd (UK)

Who is the main contact?
Dr Nisar Shah (Consultant Cardiologist, Sandwell & West Birmingham NHS Trust), sandra.payne10@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Nisar Shah

Contact details
Consultant Cardiologist
Sandwell & West Birmingham NHS Trust
Lyndon
West Bromwich
United Kingdom
B71 4HJ
+44 (0)121 507 5048
sandra.payne10@nhs.net

Type(s)
Scientific

Contact name
Dr Meik Baumeister

Contact details
The Squaire 12
Frankfurt am Main
Germany
60549
+49 69 945159910
meik.baumeister@cardis.io

Type(s)
Public

Contact name
Dr Study Team

Contact details
-
-
United Kingdom
-
None provided
info@cardis.io

Type(s)
Scientific

Contact name
Dr Gary Herbert

Contact details
-
-
United Kingdom
-

Additional identifiers

Integrated Research Application System (IRAS)
330192

Protocol serial number
SBRIH21P3013

Study information

Scientific Title
Assessing the impact of using community-based heart testing to detect early signs of cardiovascular disease through a novel, quick, low-cost screener which uses sophisticated AI-based analysis

Acronym
Cardisio - PC

Study objectives
Using 5-lead 3D-vectorcardiography with AI in primary care improves the detection of cardiovascular disease on top of the CVD-prevention pathway
1. Feasibility of using 5-lead 3D-vectorcardiography in primary care
2. User satisfaction and engagement
3. Citizens' satisfaction and engagement
4. Patient/participant-reported symptoms at inclusion
5. Improved use of resources – collection of time and resources used
6. Safety

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/06/2023, London – Camberwell St Giles Health Research Authority (2 Redman Place, Stratford , London, E20 1JQ, United Kingdom; +44 (0)207 104 8379; camberwellstgiles.rec@hra.nhs.uk), ref: 23/PR/0740

Primary study design
Observational

Study design
Multicentre partly randomized controlled non-invasive study

Study type(s)
Diagnostic

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

Interventions
Early detection of CVD
This is a multicentre, partly randomised controlled, non-invasive study, designed with a focus on the application of consistent methods and processes for recruitment and selection principles, test preparation as well as gaining consent and feedback. The study also has designed post-test processes and the role of the Secondary Care Team.

The study is designed to observe the use of the Cardisio Heart test in a range of community settings:
1. GP/PCN
2. Typical Community Pharmacy
3. Other Community settings such as faith centres or community centres

Participants will be selected using inclusion criteria that indicate some inherent risk for cardiovascular disease (CVD). This cohort of participants is estimated to be 90% negative for CVD and 10% Positive. [Note: Participants who have typical symptoms of CVD, such as chest pain or shortness of breath, will be excluded from the study and advised to seek urgent help.]

300 participants will be recruited in the GP setting, 300 in the Pharmacy setting, and 211 in the Community outreach setting.

The GP and Pharmacy site will initially select 1000 candidates and these will be randomised to 300 participants to ensure any bias in selection is minimised. The Community Outreach will recruit volunteers, unknown to the Investigator and are therefore considered to be randomised.

The study is designed to show that the Cardisio test is capable of detecting early signs of CVD and reporting this to a cardiologist who can use the results to assess and categorise patients for further observation, analysis or treatment. This will be achieved by making all the results performed, in all the study sites, available to the cardiologist in an online test results viewer. The Cardiologist will be able to sort the results in terms of severity and type of CVD (Perfusion - low blood flow to the heart muscle, structural defects, and arrhythmia issues.)

The cardiologist will use the Cardisio test result together with the patient medical and medicine history, Qrisk scores, BMI, Blood pressure and other data available to him, to make informed decisions. For each assessment made, the cardiologist will report on whether the Cardisio test information helped make a better / more informed decision.

The recruitment will take place over a 6-week period, ahead of a 10-week test period. The participants will be informed of results within 2 weeks of being tested and if positive will be offered a dedicated clinic at the time of results communication. Secondary care pathway, imaging and treatment will be subject to normal priorities. The study will conclude at the end of 2023 with a study report produced for publication.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cardisio Heart Test

Primary outcome(s)
1. Feedback from the test administrators and PIs and reported confidence of the secondary care team of the reliability of the test collected, assessed using data gathered by questionnaires and interviews at the end of the study
2. Ability of the secondary care team to successfully access test results across the study participant group, assessed using questionnaires and interviews at the end of the study
3. The number or percentage of correct predictions (true positives plus true negatives), assessed using data collected in the Cardisio system and the Study Test File gathered at each test and summarised at the end of the study
4. Number of patient journeys saved and carbon reduction estimated using postcode information at the end of the study
5. Feedback from CI and secondary team plus feedback from GP/PCN PI gathered by questionnaire and interviews at the end of the study
6. Feedback from participant surveys, feedback from PIs in pharmacy setting and analysis of referrals made, and feedback from CI and secondary care team, gathered by questionnaire and interviews. Participant questionnaires taken just before and just after the test. Other data collected during the study and analysed and summarised at the end of the study

Key secondary outcome(s)
1. Ease with which the primary care administrators can undertake recruitment selection and testing of study participants as recorded in the “Participant Testing Log”, assessed by questionnaire and interviews at the end of the study
2. Feedback on the ease of training in person and online training materials from PIs and test administrators gathered via survey and structured interviews at the end of the study
3. Feedback on the ease of test procedure and administration from PIs and test administrators gathered via survey and structured interviews at the end of the study
4. Feedback on patient experience and preference for community-based testing gathered via pre and post-test surveys at the time of each test
5. The view of the secondary care (cardiology) team of the process and impact on the quality of their patient lists, gathered via survey and structured interviews at the end of the study

Completion date
24/02/2024

Eligibility

Key inclusion criteria
1. Type 1 or Type 2 diabetes and
1.1. Aged >40 years
1.2. Insulin, metformin, sulphonylureas, alpha-glucosidase inhibitors, prandial glucose regulators, thiazolidinediones or glitazones, GLP-1 analogues (incretin mimetics), DPP-4 and SGLT2 inhibitors, statins
2. Type 1 or Type 2 diabetes aged 18 – 39 years but who have been diagnosed with one or more of the following:
2.1 Retinopathy ranibizumab (Lucentis) and aflibercept (Eylea), steroid medications
2.2 Nephropathy, including persistent microalbuminuria, persistent poor glycaemic control (HbA1c >9%) ACE inhibitors, dapagliflozin, statins, furosemide
3. Elevated blood pressure requiring antihypertensive therapy ACE inhibitor or an angiotensin-2 receptor blocker (ARB), calcium channel blockers such as amlodipine, felodipine, nifedipine, diltiazem and verapamil. Diuretics such as indapamide and bendroflumethiazide. Beta-blockers such as atenolol and bisoprolol.
4. Elevated single risk factor/s, e.g., total cholesterol >6.0 mmol/l statins
5. Features of metabolic syndrome (central obesity and fasting triglycerides) >1.7 mmol/l (non-fasting >2.0 mmol/l) As per medication for blood pressure, blood sugar and cholesterol
6. HDL cholesterol <1.0 mmol/l in men or <1.2 mmol/l in women statins, and ezetimibe, fibrates, bile acid sequestrants and bempedoic acid. Also, injections – such as alirocumab, evolocumab and inclisiran
7. Family history of premature CVD in a first-degree relative Known medication profile of a close family member taking appropriate CVD medication
OR
8. QRISK2 ≥10% or QRISK3 ≥10%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
1. Already being treated for a CVD-related condition or are symptomatic: combination of anticoagulants, blood thinners, antiplatelets, ACE inhibitors, angiotensin II receptor blockers, beta-blockers, calcium channel blockers, diuretics, vasodilators, nitroglycerin and statins
2. Age under 18 or over 75 years
3. Pregnant
4. Study conflict (participating in other studies) or unable to provide consent

Date of first enrolment
17/07/2023

Date of final enrolment
25/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Church Road Surgery
i3 Ladywood PCN
28 Church Road
Aston
Birmingham
United Kingdom
B6 5UP

Study participating centre
Dudley Health and Social Care Centre
Venture Way
Brierley Hill
United Kingdom
DY5 1RU

Study participating centre
Ridgacre HSE Pharmacy
Ridgacre House Med Ctr
83 Ridgacre Road
Quinton
Birmingham
United Kingdom
B32 2TJ

Study participating centre
Faraday Pharmacy
17 Faraday Avenue
Quinton
Birmingham
United Kingdom
B32 1JP

Sponsor information

Organisation
Cardisio UK Ltd

Funder(s)

Funder type
Industry

Funder Name
SBRI HealthCare Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the study will be stored in a publicly available repository. The team will hold the study information on our website https://cardis.io.
The type of data stored will be participants' physical attributes, sex, age, height, and weight, the reason for inclusion, results for the Cardisio test, any secondary care procedures/tests,

comments from the principal investigator regarding the quality of the referral using the Cardisio results, all statistical analysis results and outputs from the study questionnaires. The timing for availability is 1Q2024. No Participant's personal information will be published. All data will be anonymised.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			12/11/2024	No	No
Protocol file	version 1.00	04/08/2023	16/08/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes