ISRCTN47361353 https://doi.org/10.1186/ISRCTN47361353

Can we detect unknown atrial fibrillation by screening people attending dental hospital appointments?

Submission date
17/10/2022

Recruitment status
No longer recruiting

Registration date
26/10/2022

Overall study status
Completed

Last Edited
16/02/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and aims:
Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. AF affects over 1.4 million people in the UK, requires frequent hospital admissions and increases the risk of stroke five-fold. AF-related strokes are more likely to be fatal or severely disabling compared to other types of stroke. People aged 65 and over with unknown AF usually benefit from taking oral anti-coagulation medication, which reduces stroke risk in AF by two-thirds. About 5% of those aged 65 and over have AF and this may be higher in people with periodontal (gum) disease. This study will test how many people can be identified with unknown AF by simple screening at a dental hospital.

Who can participate?
Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital.
Healthcare professionals who are involved in the care of study participants

What does the study involve?
Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital:
If you take part, you will be asked to complete a simple, 30 second screening test for AF where you place your fingers on a device called KardiaMobile that is resting on a table. If the result is unclear, you will be asked to repeat the test, but this time by placing the device on your knee. If the screening detects AF, the research nurse will contact your GP so that they can discuss whether you need any treatment.

Healthcare professionals:
If you take part in the study, you will be asked to complete a telephone interview with a researcher about your experience of being involved in the care of people in the study.

What are the possible benefits and risks of participating?
Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital:
You may be diagnosed with AF as a result of the screening. This may require you to take medication to help reduce the risk of you having a stroke.

Healthcare professionals:
We do not think there are any personal benefits from participating, but your views may influence future screening programmes in dental clinics.

Where is the study run from?
Edinburgh Napier University (UK)

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

Who is funding the study?
Daiichi Sankyo UK Ltd

Who is the main contact?
Professor Lis Neubeck, l.neubeck@napier.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Coral Hanson

ORCID ID
http://orcid.org/0000-0003-1602-1968

Contact details
Room 4.B.29
Sighthill Campus
Edinburgh Napier University
Edinburgh
United Kingdom
EH11 4BN
+44 131 455 3457
c.hanson@napier.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311299

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 311299, CPMS 53463

Study information

Scientific Title
Identifying undiagnosed atrial fibrillation in older adults attending dental clinics

Acronym
DETECT-AF

Study objectives
The study aims to test if dental clinics are a suitable place to identify previously undetected AF.

Primary objective:
To identify the proportion of screened participants aged 65 years and older attending a dental clinic with newly identified AF

Secondary objective
1. To examine the correlation between periodontal health/disease status; age, sex; ethnicity; Index of Multiple Deprivation; and incidence of AF.
2. To explore the barriers and facilitators to the implementation of atrial fibrillation screening in dental clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2022, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 207 104 8091; southyorks.rec@hra.nhs.uk, ref: 22/YH/0049

Study design
Single site cross-sectional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Diagnosis of patients with atrial fibrillation

Interventions
Patients: Single time point screening for atrial fibrillation using a KardiaMobile single lead or six lead ECG device.
Healthcare professionals: one semi-structured telephone interview.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
KardiaMobile single lead or six lead ECG device

Primary outcome measure
The proportion of participants aged 65 years and older attending a dental clinic that take part in single time point atrial fibrillation screening using a KardiaMobile single lead or six lead device that are diagnosed with newly identified atrial fibrillation.

Secondary outcome measures
At a single time point:
1. Periodontal health/disease status (most recent basic periodontal score retrieved from patient records)
2. Age, sex; ethnicity; Index of Multiple Deprivation quintile (calculated from postcode)
3. Incidence of atrial fibrillation (as per the primary outcome measure)
4. The barriers and facilitators to implementing atrial fibrillation screening in dental clinics identified via semi-structured interviews with healthcare professionals and student healthcare professionals involved in the screening study.

Overall study start date
01/03/2022

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Patients:
1. Adults aged 65 years and over
2. Being a patient of the Newcastle dental hospital
3. Able to give informed consent
4. Due to time and financial constraints surrounding the cost translation services and qualitative data transcription, the study will be unable to recruit participants who cannot adequately understand verbal explanations or written information given in English.

Healthcare professionals:
5. Healthcare professionals (and student healthcare professionals) who have been involved in the care of patients who are participating in the study.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
65 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
Patients:
1. Have been diagnosed with severe co-existing conditions (severe dementia or terminal illness)
2. Are unable to give informed consent
3. Due to time and financial constraints surrounding the cost translation services and qualitative data transcription, the study will be unable to recruit participants who cannot adequately understand verbal explanations or written information given in English

Healthcare professionals:
4. Dental hospital staff/students who are not working at the Newcastle Dental Hospital and not involved in the care of study participants
5. GPs who are not involved in the care of study participants

Date of first enrolment
02/11/2022

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Dental Hospital
Richardson Road

Newcastle upon Tyne
United Kingdom
NE2 4AZ

Sponsor information

Organisation
Edinburgh Napier University

Sponsor details
Sighthill Court
Sighthill
Edinburgh
Scotland
United Kingdom
EH11 4BN
+44 131 455 6009
p.stevenson@napier.ac.uk

Sponsor type
University/education

Website
http://www.napier.ac.uk

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Industry

Funder Name
Daiichi Sankyo UK Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/10/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Data generated by the project will be made open after completion of the project once appropriate changes (e.g., all participants assigned a unique identifier and any identifying details have been removed) have been made to honour assurances of confidentiality and anonymity. The Information Commissioner's Office Anonymisation: managing data protection risk code of practice will be adhered to: https://ico.org.uk/media /fororganisations/ documents/1061/anonymisation-code.pdf. Datasets will be allocated a DOI and stored on the Edinburgh Napier University Open Access Research Repository in accordance with the University research data deposit process.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Phase 1 version 4	24/08/2022	25/10/2022	No	Yes
Participant information sheet	Phase 2 version 4	24/08/2022	25/10/2022	No	Yes
Protocol file	version 6	20/07/2022	25/10/2022	No	No
HRA research summary			28/06/2023	No	No