

AMALFI: Active monitoring for atrial fibrillation

Submission date 20/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/05/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/02/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

AMALFI is a randomized trial of screening for undiagnosed atrial fibrillation (AF - a type of irregular heartbeat) in people thought to be at high risk of having the condition.

Who can participate?

Anyone over 64 years old with a CHA2DS2-VASc score ≥ 3 in men or ≥ 4 in women. (CHA2DS2-VASc = Congestive heart failure, Hypertension, Age, Diabetes, Stroke, Vascular disease).

What does the study involve?

The trial aims to randomize 2500 participants in the UK, half of which will wear a CE-marked medical device called the Zio Patch. This is a self-applied ECG monitor that is worn for 2 weeks to assess for signs of AF even if the participant feels well. The intention is to assess the rate of undiagnosed AF to see if earlier detection (and therefore treatment) of undiagnosed AF is worthwhile and results in improved healthcare. If eligible and randomized to wear a patch, they will be sent the device and instructions on how to apply it. After wearing the device for two weeks, it will be returned for analysis and the results sent to their GP who may use the information to decide on the appropriate management. Those not randomized to wear a patch will continue on their usual care.

What are the possible benefits and risks of participating?

Benefits:

Participants who are randomized to receive a Zio Patch will either be reassured that their heart is functioning normally

or they will have a previously undiagnosed AF brought to their GP's attention and therefore their risk of having a stroke

may have been substantially lowered.

If the research is successful, there is a possibility that it may result in a national screening programme that would benefit everyone.

Risks:

Some participants who are randomized to the group who do not wear the Zio Patch may be disappointed that having volunteered to help, they are not allocated a patch to wear. They may also worry about their chance of having an irregular heart beat that is not detected. Our gratitude for their contribution and the importance of having a control group is made clear in

the literature and on the website, so hopefully they will understand the importance of their role. Advice on AF is available in the information provided and if they are still concerned, we recommend that they should see their GP in the usual way.

For those randomized to wear the Zio Patch; there is a chance that the patch may cause a minor irritation to the skin and therefore may cause some unforeseen discomfort to some participants. Individuals with certain skin conditions are recommended not to participate in the study. There is information available in the literature and on the website; we also have a 24-hour Freephone service for anyone who is worried and needs medical or practical advice about the Zio Patch.

If AF is diagnosed from the patch report and an individual's GP decided that treatment is required, the medication can carry some potential risks. However, the care is standard throughout the UK and would have been offered to the participant if AF became apparent to the GP outside of the study. Although earlier diagnosis may mean that the participant receives a longer period on medication, their risk of having a stroke with its associated risks may have been substantially lowered

Where is the study run from?

Clinical Trial Service Unit, Nuffield Department of Public Health, University of Oxford, UK.

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

The study starts in May 2019 and data collection will continue for up to 25 years.

Who is funding the study?

1. NIHR Oxford Biomedical Research Centre (UK)
2. British Heart Foundation (UK)

Who is the main contact?

1. Ms Karen Taylor (public)
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2. Prof. Louise Bowman (scientific)
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Study website

<https://www.amalfitrial.org>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
234837

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41053

Study information

Scientific Title
AMALFI (Active Monitoring for Atrial Fibrillation): A randomized controlled trial of screening for silent atrial fibrillation in high-risk individuals.

Acronym
AMALFI

Study objectives

To assess the effect of 2 weeks of continuous monitoring using Zio Patch on the proportion of participants diagnosed with atrial fibrillation (AF) compared to usual care at 2.5 years of follow up from randomization (i.e. at around the midpoint of a proposed 5-year screening interval).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/01/2019 London - Bromley REC (Metropolitan Police Hayes Sports Club, The Warren, Croydon Road, BR2 7AL; 0207 104 8209; nrescommittee.london-bromley@nhs.net) ref: 19/LO/0220.

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

<https://www.amalfitrial.org/about>

Health condition(s) or problem(s) studied

Atrial fibrillation

Interventions

Eligible participants will be identified via an electronic search of GP practice data, identifying individuals with risk factors (such as diabetes or high blood pressure) that put them at an increased risk of having a stroke. Men and women aged 65 and over, with a high-risk score, will be approached by mail by their GP and offered the opportunity to participate in the study.

If eligible and randomized to wear a patch, they will be sent the device and instructions on how to apply it. After wearing the device for two weeks, it will be returned for analysis and the results sent to their GP who may use the information to decide on the appropriate management. Those not randomized to wear a patch will continue on their usual care.

If allocated to the study arm that is not required to wear the patch, the participant will receive a letter thanking them for their contribution. No further input is required from the participant.

Following the initial phase, all participants will continue with their normal care. At 1, 2½ and 5 years after randomization data will be collected from the GP records to assess the proportion of

participants diagnosed with AF (as recorded in the electronic GP record) and to see if having AF diagnosed earlier, made a difference to their medical care and stroke rate.

Intervention Type

Other

Primary outcome measure

To assess the effect of 2 weeks of continuous monitoring using Zio Patch on the proportion of participants diagnosed with AF compared to usual care at 2.5 years of follow up from randomization (i.e. at around the midpoint of a proposed 5-year screening interval).

Secondary outcome measures

Following the initial phase, all participants will continue with their normal care. At 1, 2½ and 5 years after randomization data will be collected from the GP records to assess the proportion of participants diagnosed with AF (as recorded in the electronic GP record) and to see if having AF diagnosed earlier, made a difference to their medical care and stroke rate.

Overall study start date

25/03/2019

Completion date

01/09/2044

Eligibility

Key inclusion criteria

1. Male or Female, aged ≥ 65 years old.
2. CHA2DS2-VASc score ≥ 3 in men or ≥ 4 in women.
3. Willing and able to give informed consent for participation in the study.

Participant type(s)

Patient

Age group

Senior

Lower age limit

65 Years

Sex

Both

Target number of participants

5000

Total final enrolment

5043

Key exclusion criteria

1. Known to have AF or atrial flutter
2. Latex allergy (given the potential for an allergic reaction to the Zio Patch)

Date of first enrolment

01/05/2019

Date of final enrolment

31/01/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Trial Service Unit Nuffield Department of Public Health

University of Oxford

Old Road Campus

Roosevelt Drive

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Sponsor information

Organisation

University of Oxford

Sponsor details

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RGEA.Sponsor@admin.ox.ac.uk

Sponsor type

University/education

Website

<https://researchsupport.admin.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

NIHR Oxford Biomedical Research Centre

Alternative Name(s)

NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Funder Name

British Heart Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/09/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		11/04/2019	21/05/2019	No	No
Protocol file	version 1.2	09/09/2019	03/01/2020	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	08/06/2021	20/02/2025	No	No