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# AMALFI: Active monitoring for atrial fibrillation

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| **Submission date**<br>20/05/2019 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>21/05/2019 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>20/02/2025 | **Condition category**<br>Circulatory System | [_] Individual participant data<br>[X] 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 bought 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)
amalfi@ndph.ox.ac.uk
2. Prof. Louise Bowman (scientific)
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### Study website
https://www.amalfitrial.org

# Contact information

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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
Roosesvelt Drive
Headington
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OX3 7LF

## Sponsor information

### Organisation
University of Oxford

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Joint Research Office
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Churchill Drive
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Oxford
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United Kingdom
OX3 7GB
+44 (0)1865 572221
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 |