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OpenEP|NET

Submission date 21/08/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/10/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 30/10/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiac arrhythmias (variations in the heartbeat) occur in about one-in-four people. They can impact broadly on quality
of life and dramatically increase health risks. The most frequent arrhythmia is atrial fibrillation. Atrial fibrillation
increases risks of health failure nearly five-fold, chronic kidney disease by 64%, coronary heart disease by 61% and
stroke 2.3-fold. Women have worse outcomes overall than men. Ventricular arrhythmias are the leading cause of
sudden cardiac death, responsible for 6 million annual fatalities.
Arrhythmias are often treated by procedures called Ablation or device implantation. Ablation is a specialised process
where small patches of tissue are destroyed under anaesthetic. Devices used for treating arrhythmias include
pacemakers (which keep the heart going at the right speed) and defibrillators (which reset the heartbeat if it goes
wrong). Ablation is an intricate and costly procedure which only provides an effective long-term solution in 50-80% of
patients, and we still don't fully understand its benefits.
During these treatments doctors collect an enormous amount of data. This includes details on the heart's structure
and its electrical activity triggering and regulating the heartbeat. This data is stored in various stand-alone formats
which makes it difficult to compare and analyse on a large scale. As a result, big data research has not progressed in
this field compared to other fields. To solve this problem our team developed a software tool named OpenEP. This
software can dramatically reduce the size of the collected heart data which makes it far simpler to analyse.
In this programme of research, we will use OpenEP, along with other tools, to make arrhythmia data accessible to
researchers. To ensure broad applications, we will link routinely collected data to important

clinical outcomes, such as
heart attacks, strokes, or hospital admissions, and patient reported outcomes such as symptoms providing an end-to-end trace from data to outcomes.

Who can participate?
Patients aged 18 years or over undergoing electrophysiological assessment (electroanatomic mapping, cardiac implantable device recordings or ECG recordings)

What does the study involve?
Patients will be able to opt out of the cohort and consent will be sought for inclusion when patients are approached to take part in future studies within the Programme. Once part of the cohort, patients who have consented may be approached to take part in other arrhythmia studies which will be added under this approval. These are smaller studies that focus on specific important health questions. These studies will either use data already collected or will require extra visits from participants.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
June 2026 to December 2029

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Steven Williams, steven.williams@ed.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Central Portfolio Management System (CPMS)

64587

Grant Code
UKRI1480

Study information

Scientific Title
OpenEP|NET

Study objectives
The objectives of the OpenEP|NET Programme of Research are to:
1. Create a multi-centre cohort of arrhythmia patients
2. Study the links between arrhythmia data, clinical features and treatment responses and analyse the impact on long-
term outcomes
3. Maximise the impact of OpenEP|NET through future studies within the Programme

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/09/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Floor 4 Crown Building, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC2@wales.nhs.uk), ref: 25/WA/0276

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Treatment

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

Interventions
The OpenEP|NET Programme of Research will be a large UK-based study. It will track the health of patients with arrhythmias over time. It will gather detailed heart mapping data during patient treatments. The study team will convert this data into a special format (OpenEP), and store it securely for research. By connecting these data to patients' health outcomes nationwide, OpenEP|NET will allow us to understand more about health outcomes associated with arrhythmias.

The cohort will initially consist of a large unconsented dataset collected under Confidentiality Advisory Group and Public Benefit and Privacy Panel approvals. Individuals will be able to opt out of the cohort, and consent will be sought for inclusion in the cohort when patients are approached to take part in future studies within the Programme. We are seeking approval to use

routinely collected unconsented data because previous studies have not represented all groups of the population. Our proposed approach will mean that study findings can help the widest possible group of patients.

Once part of the cohort, individuals who have consented may be approached to take part in other arrhythmia studies which will be added under this approval. These are smaller studies that focus on specific important health questions. These studies will either use data already collected, or require extra visits from participants. These are overseen by the OpenEP|NET Steering Committee and the program's Sponsor. We will also seek to establish a Research Database to facilitate data-only research and ensure the maximum benefit is derived from this hugely rich dataset. We will store data within a special system called a Trustworthy Research Environment, or TRE. The TRE will make sure that patient data is stored securely. The TRE is provided by a nationally recognised and trusted company called ARO and is a cloud-based computer system. The TRE consists of several components, which together ensure secure and effective storage and analysis of data.

Researchers at enrolling study sites will be able to log into the TRE to securely enter relevant information. Part of this process will involve the transfer of large files, which will be handled through a secure website. Within the TRE, each study participant will be given a unique identifier. This identifier ensures that data from more than one hospital can be reliably linked together. Importantly it also ensures that researchers undertaking day-to-day analysis of data will have no sight of an individual's personal details.

Researchers will be able to log into a separate place in the TRE to securely access this study data. This will only be the data needed by that researcher to study a specific research question. The data for these studies will be prepared by the core OpenEP|NET team to ensure that only the data required is made available.

Within the TRE, researchers will have access to the software they need to conduct their research. As well as all the general research software for analysing data, this will also include two important pieces of software - OpenEP and EP Workbench. OpenEP provides a data format for storing electrophysiology data. This is important since electrophysiology data is currently stored in lots of different incompatible formats, depending on which system is being used. OpenEP standardises this data across different equipment manufactures ensuring that researchers have critically a standard set of data to work with. EP Workbench provides an easy to use page for working with OpenEP data. Making a comparison with standard computer software, EP Workbench is like a word processor (e.g., Word) whilst OpenEP is like a document format (e.g. 'docx'). Together, OpenEP and EP Workbench will allow researchers to undertake their research for the first time easily and efficiently.

The TRE will also provide:
1. Statistics to the study website, for example describing enrolment to the study. This will provide a single point of access for study participants where they can see the progress of the study and other statistics critical to the research.
2. The ability to export data for further analysis using special computer systems. A "Digital Air Lock" will ensure that only data the participants have agreed to be shared, or which is fully anonymised, will be created.
3. The ability to combine data from other trusted systems. This will allow future linkage to systems recording diverse and important information, perhaps relating to blood tests or environmental exposures and "future proofing" the system to utilise as yet undefined data.

Together these features will ensure the greatest possible impact from the proposed research.

Intervention Type
Other

Primary outcome(s)
1. All-cause mortality, ischaemic stroke, transient iscahemic attack or hospitalization for heart failure, measured using linkage with hospital episode statistics at 1 year

Key secondary outcome(s)

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Patients undergoing electrophysiological assessment (electroanatomic mapping, cardiac implantable device
recordings or ECG recordings)
2. Aged 18 years or over

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Potential participant has registered their intention for their data not to be used for research, via the national-data optout (NHS England sites only)
2. Potential participant has registered their intention for their data not to be used for research, via direct communication
with their healthcare provider or the OpenEP|NET team
3. Aged <18 years

Date of first enrolment
01/01/2026

Date of final enrolment
31/12/2029

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
University of Edinburgh
Chancellor's Building
49 Little France Crescent
Edinburgh
Scotland
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository

IPD sharing plan summary
Stored in non-publicly available repository