ISRCTN10278811 https://doi.org/10.1186/ISRCTN10278811

Ambulatory ECG monitor versus standard care in acute unexplained syncope (sudden loss of consciousness also known as blackout or fainting)

Submission date
25/03/2022

Recruitment status
No longer recruiting

Registration date
19/04/2022

Overall study status
Ongoing

Last Edited
23/04/2025

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Syncope (sudden loss of consciousness also known as blackout or fainting) causes over 600,000 people to visit emergency departments every year in the UK. Often, by the time the patient is seen by the medical team they have fully recovered making it hard to diagnose the underlying problem. A mobile heart ECG monitoring device has recently been developed (BodyGuardian Mini; Preventice Solutions). This device can record the patient's heartbeat and heart electrical rhythm tracing for up to 14 days. By wearing the mobile heart monitor after attendance at the Emergency Department there may be a better chance of finding an underlying problem that caused the blackout. This study aims to recruit people who, after investigation at the Emergency Department a cause hasn't been found for their episode of blackout. The goal is to discover if by providing patients with a 14-day mobile heart ECG monitor, doctors can better diagnose and treat the cause of a sudden loss of consciousness and reduce the number of further episodes and their potential serious consequences (i.e. injury, anxiety, poor quality of life and on rare occasions, death), reduce hospital admissions, reduce overall health costs and increase quality of life. At the moment it is not known how long patients who have this type of monitor should be monitored for, so this study will also answer this question.

Who can participate?
Adults aged 16 years or older who attend hospital following a blackout, and after initial assessment it is still unclear what caused the blackout.

What does the study involve?
Participants are allocated to one of two groups. One group will be fitted with the mobile heart monitor to wear for 14 days and will also receive standard care which may mean being referred to a specialist clinic in the hospital. The other group will not be given the heart monitor but will receive standard care which may include the use of a standard heart monitor and being referred to a specialist clinic in the hospital. Everyone who takes part in the study will be contacted once a month for 2 years either by text, email or phone call to complete a very brief questionnaire

comprising of two questions. Participants will also be asked to complete a quality-of-life questionnaire when they start the study and in 1 and 2 years' time asking how they are feeling and about day-to-day activities. Finally in 1 years' time participants will be asked to complete a satisfaction questionnaire.

What are the possible benefits and risks of participating?
For the group allocated to wear the 14-day mobile heart ECG monitor, there is the possibility that the researchers may find a heart-related problem that may not have been detected otherwise. This information would be shared with the Specialist team at the hospital to arrange appropriate further tests and treatments as necessary. Otherwise, there are no direct benefits to taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

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

When is the study starting and how long is it expected to run for?
August 2021 to June 2026

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
1. Dr Matthew Reed - Chief Investigator
mattreed@ed.ac.uk
2. Lynn Dinsmore - Trial Manager
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Study website
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study

Contact information

Type(s)
Public

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Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304917

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52042, Protocol Number AC21115, IRAS 304917

Study information

Scientific Title
Multi-centre open-label randomised controlled trial of immediate enhanced ambulatory ECG monitoring versus standard monitoring in acute unexplained syncope patients: the ASPIRED study.

Acronym
ASPIRED

Study objectives
To determine whether the immediate application of enhanced mobile heart monitoring will decrease the number of episodes of blackouts at 1 year compared to standard care monitoring in patients attending hospital with acute unexplained blackouts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2021, South East Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 536 9000; sandra.wyllie@nhslothian.scot.nhs.uk), ref: 21/SS/0073

Study design
Multi-centre open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study

Health condition(s) or problem(s) studied
Early diagnosis of patients presenting to Emergency Departments with undiagnosed syncope (blackouts).

Interventions

Participants will be randomised, 1:1, between the two study arms. Randomisation will be performed using a web-based randomisation service to ensure allocation concealment. The allocation sequence will be created by a database programmer using computer-generated pseudo-random numbers. Stratification by site will be used to ensure balanced randomisation.

Participants randomised to the intervention arm will be fitted with a 14-day ambulatory heart monitor (Preventice BodyGuardian Mini) applied by the study team as soon after ED attendance and randomisation as possible. The participant will wear the ambulatory ECG monitor for a maximum of 14 days after which they will remove the monitor and return it to Preventice UK for reporting by an ECG technician. The ECG report will be shared with the local study team.

Participants in both control and intervention arms will receive standard care which will include all care usually given to unexplained syncope patients at each participating site along with some form of standard care monitoring such as but not limited to wired inpatient telemetry, Holter style monitoring or implantable loop recorder.

All participants will be followed up for 2 years from randomisation through hospital records, questionnaires and participant-reported events.

Participants will be contacted at monthly intervals throughout the study follow-up by automated text or email (participant preference) with a link to a brief web-based questionnaire. Those who are unable to access digital forms of communication will receive phone calls. Participants will also be contacted at 1 and 2 years to complete a quality-of-life questionnaire. The participants' involvement in the study will cease at 2 years.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Boston Scientific Cardiac Diagnostics BodyGuardian Mini Ambulatory ECG Monitor

Primary outcome measure
Number of self-reported episodes of syncope at 1 year. Participants will be contacted at monthly intervals throughout the study follow-up which will last for 2 years, by automated text or email (participant preference) with a link to a brief web-based questionnaire asking for the number of syncope events experienced since their last response and how many of these they attended hospital for. Those who are unable to access digital forms of communication will receive phone calls.

Secondary outcome measures
1. Within trial cost-effectiveness (cost per syncope avoided and cost per quality-adjusted life-year [QALY] gained), and lifetime cost per QALY at (a) 1 year and (b) 2 years measured by NHS resource utilisation data and EQ-5D-5L questionnaires.
2. Number of self-reported episodes of syncope at (a) 90 days and (b) 2 years, those identified in the medical records at (c) 90 days, (d) 1 year and (e) 2 years, and syncope recurrence rate at (f) 90 days, (g) 1 year and (h) 2 years measured from 4 weekly patient brief questionnaire and extraction of NHS resource utilisation data.
3. Index presentation hospital (a) admission rate and (b) duration of hospital stay measured

using NHS resource utilisation data at 90 days 1 year and 2 years.
4. Patient satisfaction measured using a patient questionnaire at 1 year
5. Clinically significant cardiac dysrhythmia (serious and/or symptomatic cardiac dysrhythmia at (a) 90 days, (b) 1 year and (c) 2 years measured from NHS resource utilisation data.
6. (a) 30-day, (b) 1-year and (c) 2-year all-cause death as recorded from NHS resource utilisation data
7. Detection of diagnostic ECG/symptom correlation (symptomatic) at (a) 90 days, (b) 1 year and (c) 2 years measured from NHS resource utilisation data and participant self-reported 4 weekly brief questionnaires.
8. Time to detect clinically significant cardiac dysrhythmia (i.e. time to clinician being aware) measured from NHS resource utilisation data at 90 days, 1 year and 2 years. For the intervention group data from the ambulatory ECG monitoring report which will be provided at the end of the 14-day monitoring period.
9. In the intervention group, the duration of enhanced ambulatory ECG monitoring required to detect clinically significant cardiac dysrhythmia measured using data from the ambulatory ECG monitoring report at 90 days
10. Number and type of diagnostic tests and therapeutic interventions at (a) 1 year and (b) 2 years measured from the NHS resource utilisation extraction data

Overall study start date
01/08/2021

Completion date
24/06/2026

Eligibility

Key inclusion criteria
1. Syncope remains unexplained after initial ED/AMU assessment.
2. Aged ≥16 years
3. Patient has capacity
4. Local resident (i.e. resident within local health board so will not be lost to medical record follow up)
5. Less than five self-reported episodes of syncope in the previous month

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
2,234

Total final enrolment
2234

Key exclusion criteria
1. Obvious underlying cause after assessment:
1.1. Features of vasovagal syncope AND absence of structural heart disease AND normal physical examination AND normal ECG
1.2. Dysrhythmia on pre-hospital or hospital ECG as likely cause of syncope
1.3. Postural hypotension (symptomatic postural drop >20 mmHg AND suggestive history)
1.4. Confirmed diagnosis of Pulmonary Embolus or Acute Myocardial Infarction
1.5. Radiological diagnosis or clinical signs/symptoms of cerebrovascular accident/transient ischemic attack or subarachnoid haemorrhage
1.6. Evidence of:
1.6.1. Haemorrhage
1.6.2. Alcohol or illicit drugs
1.6.3. Epileptic seizure
1.6.4. Hypoglycemia
1.6.5. Head trauma
1.6.6. Other obvious cause of syncope as presumptive cause of TLoC
2. Inability to consent
3. Previous recruitment into the study
4. Patient in custody or prison
5. Aged <16 years
6. Patient does not reside within local health board and will therefore be lost to medical record follow up
7. Five or more self-reported episodes of syncope in the previous 4 weeks

Date of first enrolment
15/07/2022

Date of final enrolment
24/06/2024

Locations

Countries of recruitment
England

Jersey

Scotland

United Kingdom

Wales

Study participating centre
Royal Infirmary of Edinburgh
NHS Lothian

51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Taunton Hospital
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
NHS Fife
Hayfield House
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1FR

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
St Johns Hospital
Howden West Road
Livingston
United Kingdom
EH54 6PP

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre

Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
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S5 7AU

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Jersey General hospital
Gloucester Street
St Hellier
Jersey
JE1 3QS

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd

Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre
University Hospital of North Tees
Hardwick road
Stockton -on- Tees
United Kingdom
TS19 8PE

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
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S44 5BL

Study participating centre
Kettering General Hospital
Rothwell Road
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NN16 8UZ

Study participating centre
Warwick Hospital
Lakin Road
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CV34 5BW

Study participating centre
University Hospital Ayr
Dalmellington Road
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United Kingdom
KA6 6DX

Study participating centre

North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Milton Keynes General Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre

Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
United Kingdom
PA2 9PN

Study participating centre
Hull Royal Infirmary
Anlaby Road
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HU3 2JZ

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
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SP2 8BJ

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Lincoln County Hospital
Greetwell Road

Lincoln
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LN2 5QY

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
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Newham University Hospital NHS Trust
Newham General Hospital
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E13 8SL

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Gloucester Royal Hospital
Great Western Road
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Study participating centre
Salford Royal Hospital
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United Kingdom
M6 8HD

Study participating centre
Queens Hospital
Belvedere Road
Burton-on-trent
United Kingdom
DE13 0RB

Study participating centre
Kings College Hospital
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London
United Kingdom
SE5 8AB

Study participating centre
University College London Hospitals NHS Foundation Trust
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United Kingdom
NW1 2PG

Sponsor information

Organisation
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Sponsor type

University/education

Website
http://accord.scot/

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
Anonymised study Individual participant data (IPD) and metadata generated and/or analysed during the current study will be available on request. In the first instance, email requests should be made via email to ECTUdatashare@ed.ac.uk. Study data and metadata will be available for as long as it has been retained. Once the completed application form has been received, a review panel will review the application form. The review panel will consider the following: Permissions listed in ASPIRED Ethics/Patient Information Sheet Consent Form (PISCF); Risk of identification; Risk of affecting ASPIRED study outcomes/data access embargo date; Stage of study; Requester evaluation (e.g. relationship to Chief Investigator, Edinburgh Clinical Trials Unit
etc); Scientific merit of proposed data use; Overlap with other study projects; and Permissions (i.e. ethical, information governance) in place for proposed data use.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/02/2023	24/02/2023	Yes	No
Other publications	Results from an embedded qualitative study focused on patient and healthcare professional usability and acceptability	08/04/2025	23/04/2025	Yes	No