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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
25/03/2022		[X] Protocol		
Registration date	Overall study status Ongoing Condition category	Statistical analysis plan		
19/04/2022		Results		
Last Edited		Individual participant data		
23/04/2025	Signs and Symptoms	[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 Lynn.Dinsmore@ed.ac.uk

Contact information

Type(s)

Public

Contact name

Mrs Lynn Dinsmore

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Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

304917

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

ΔII

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

United Kingdom

England

Scotland

Wales

Jersey

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 United Kingdom 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 HospitalWestminster 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 Calow Chesterfield United Kingdom S44 5BL

Study participating centre Kettering General Hospital

Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Warwick Hospital

Lakin Road Warwick United Kingdom CV34 5BW

Study participating centre University Hospital Ayr

Dalmellington Road Ayr 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

Hull

United Kingdom HU3 2JZ

Study participating centre Salisbury District Hospital Salisbury District Hospital Odstock Road Salisbury

United Kingdom 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 United Kingdom 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

Wrexham United Kingdom LL13 7TD

Study participating centre Newham University Hospital NHS Trust

Newham General Hospital Glen Road London United Kingdom E13 8SL

Study participating centre Gloucester Royal Hospital

Great Western Road Gloucester United Kingdom GL1 3NN

Study participating centre Salford Royal Hospital

Stott Lane Eccles Salford United Kingdom M6 8HD

Study participating centre Queens Hospital

Belvedere Road Burton-on-trent United Kingdom DE13 0RB

Study participating centre Kings College Hospital

Mapother House De Crespigny Park Denmark Hill London United Kingdom SE5 8AB

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

Sponsor information

Organisation

The University of Edinburgh and Lothian Health Board ACCORD

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

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
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes