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ASPIRED study - Brief summary for potential sites.

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

Funding: British Heart Foundation
Sites will receive a per patient fee of £100
We will apply for the study to be on the NIHR CRN Trauma and Emergencies portfolio
Planned first patient recruitment: 1st March 2022

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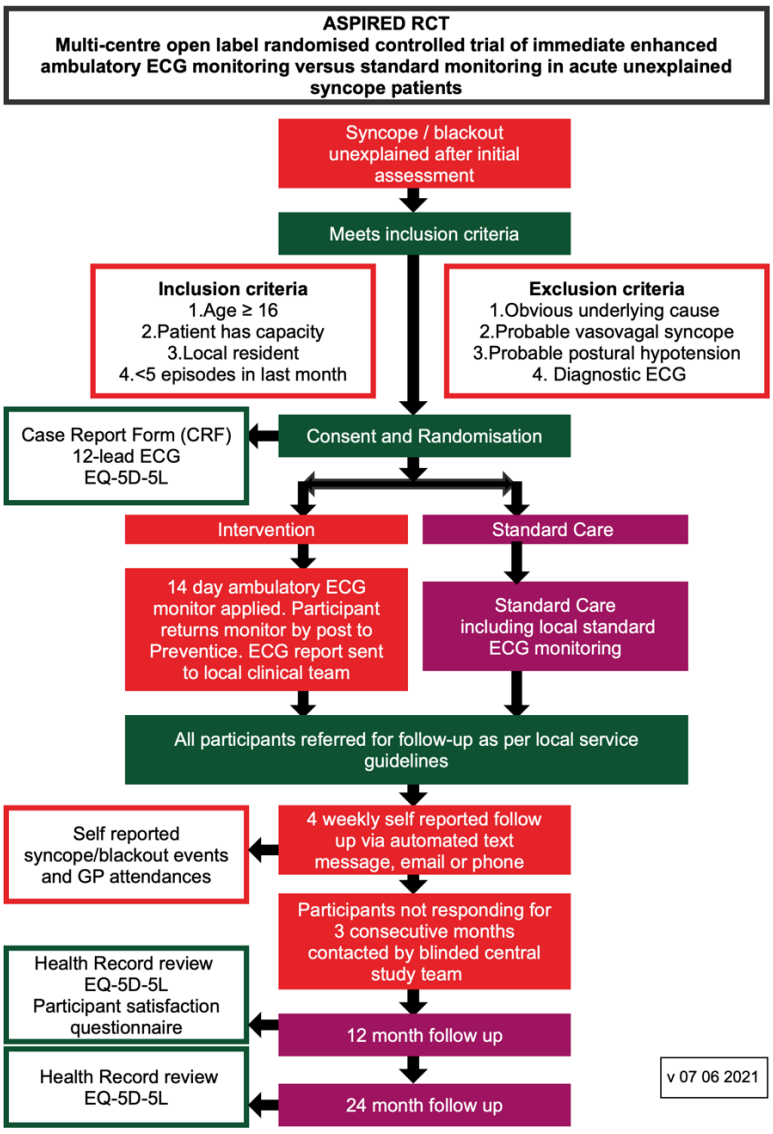


ASPIRED is an open prospective parallel group randomised controlled trial of a 14-day ambulatory heart ECG monitor (BodyGuardian Mini; Preventice Solutions) applied to patients versus standard care monitoring in patients presenting acutely with unexplained syncope.

2234 adult (16 years or older) participants presenting acutely to UK hospitals with syncope remaining unexplained after initial assessment will be recruited in ~26 NHS acute tertiary and district hospitals. Participants will be randomised, 1:1, between the two study arms. Randomisation will be performed using a web-based randomisation service

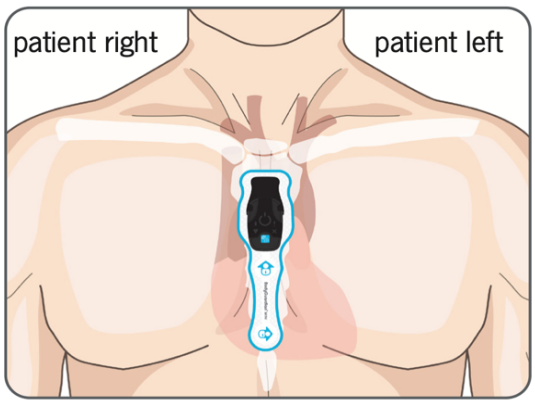
The study will be conducted over 4 years. Recruitment will take place over 18 months. All participants will be followed-up for 2 years after index event.

Potential participants will be identified from ED/AMU departments or other acute settings whilst in hospital or using electronic medical records after discharge. Potential participants who are not approached in hospital (e.g. as they attend out of hours or lack of study team availability) will be identified using electronic medical records or through referral from the clinical team and contacted by phone by the research team to invite them to take part in the study.

Participants will have a CRF completed at randomisation, comprising demographic, historical and examination characteristics, Canadian Syncope Risk Score (recording troponin only if measured), 12-lead ECG, and disposition (admission/discharge). Participant contact details (email and contact phone number) will be confirmed along with preferred method of self-reporting of further episodes (text or email). Participant disposition (i.e. admission/discharge) will be at the discretion of the treating clinician.

All recruited participants regardless of allocation group, will be referred for syncope assessment as per local service protocol (e.g., cardiology /general medicine/ syncope specialist /ambulatory care) to be seen ideally within 4-6 weeks of the index event especially if the participant was discharged directly from the ED or if syncope assessment did not occur during the participant's index admission. Subsequent investigation should be arranged at the discretion of the treating clinician, based on local guidance and the participant's history and frequency of TLoC.

Participants randomised to the intervention arm will be fitted with a 14-day ambulatory heart monitor (Preventice BodyGuardian Mini) applied by the study team during the initial admission, or if discharged ideally within 72 hours of the initial admission but as soon after ED attendance and randomisation as possible. The ambulatory ECG monitor will be placed on the participant's chest wall over the sternum (middle bony area of chest) in the ED. It is connected directly to an ECG electrode sticker (see **figure** below). It is the size of a watch face, is non-invasive, water-resistant and is discrete to wear. It continuously monitors the heart for up to 14 days including during sleep, in the shower, and during moderate exercise. It does not impact on activities of everyday life such as showering, swimming and other exercise, or a participant's choice of clothes especially in warmer weather, as it sits comfortably underneath these. The participant's skin does not require shaving but is cleaned prior to attaching the device, which are easily removed by the participant after 14 days. The monitor can be worn by both women and men.



(Figures from https://www.preventicesolutions.com with permission)

The participant will wear the ambulatory ECG monitor for 14 days after which they will simply remove the ambulatory ECG monitor and return it in a pre-paid envelope to Preventice UK. No identifiable patient details will be sent to Preventice. The monitor will be reported by an ECG technician and Preventice UK will share the reported ECG identified by study number with the participant's local study team who will share it with the treating clinician and treating team to whom the participant has been referred for specialist syncope assessment as per local service protocol.

Any study participant with a serious dysrhythmia on the ECG report will be contacted as soon as possible by the local team and managed appropriately according to local policy. This process worked well in our pilot study. Treatment of device findings will be at the discretion of the treating clinician at each site.

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

Participants will be contacted at monthly intervals throughout the study follow-up which will last for 2 years, by text or email (participant preference) with a link to a brief web based questionnaire asking for the number of syncope events experienced since last response and if they have had any scheduled or unscheduled healthcare episodes or investigations related to syncope outwith their base hospital since last response. Those who are unable to access digital forms of communication will receive phone calls.

Participants will also be contacted at one and two years by the central study team to complete a quality of life questionnaire. The participants' involvement in the study will cease at 2 years.

The study primary objective is to determine whether immediate, enhanced (14-day) ambulatory ECG monitoring decreases the number of episodes (identified in the medical records and self-reported) of syncope at one year compared to standard care monitoring in acute unexplained syncope patients.