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Implantable loop recorder for continuous beat-to-beat monitoring (REVEAL) versus conventional strategy in the analysis of syncope of unknown aetiology

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/12/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 26/08/2009	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
1. Compare the diagnostic yield and time to diagnosis of the REVEAL with the diagnostic yield and time to diagnosis of a conventional diagnostic approach
2. Test the hypothesis that REVEAL can improve quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
Implantable loop recorders.
Conventional strategy includes external loop recording, and (if necessary) repeating of 24 hours holter monitoring, echocardiography or exercise-ECG.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Diagnostic yield defined as number of patients with arrhythmias with symptoms + number of patients with sinus rhythm with symptoms divided by the total number of patients undergoing the test.

Key secondary outcome(s))
1. Quality of life
2. Cost-analysis

Completion date
31/07/2003

Eligibility

Key inclusion criteria
1. No diagnosis after history, physical exam and ECG
2. No diagnosis after echocardiography
3. No diagnosis after 24 hours holter monitoring
4. No diagnosis after exercise-testing
5. Age >18 years, <80 years
6. At least one syncopal episode with trauma or 2 witnessed syncopal episodes
7. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. (Cardiac) High risk patients
2. Abnormal electrophysiological examination
3. Pace-maker or intra-cardiac defibrillator
4. Pregnancy
5. Not able to activate implantable loop recorder
6. Serious disease with life expectancy <2 years

Date of first enrolment
01/01/2000

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
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1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Dutch Heart Foundation (Netherlands)

Alternative Name(s)
Heart Foundation

Funding Body Type
Private sector organisation

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

Location
Netherlands

Funder Name
Medtronic BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration