

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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

Netherlands

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