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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

Registration date
19/12/2005

Overall study status
Completed

Last Edited
26/08/2009

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
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.

Secondary outcome measures
1. Quality of life
2. Cost-analysis

Overall study start date
01/01/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
85

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)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration