Extended rhythm SCreening for AtRial Fibrillation in cryptogenic stroke patients

Published: 26-07-2011
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To establish evidence on the effectiveness of long term rhythm observation using an implantable loop recorder for detecting atrial fibrillation in patients with cryptogenic stroke.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON41263

Source
ToetsingOnline

Brief title
SCARF

Condition

- Cardiac arrhythmias
- Central nervous system vascular disorders

Synonym
stroke cerebrovascular accident

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: atrial fibrillation, cryptogenic, stroke

Outcome measures

Primary outcome

The percentage of patients with documented AF based on implantable cardiac monitor registration during a follow-up period of at least 12 months after an episode of cryptogenic stroke. Compared to usual care consisting of an 12 lead ECG upon outpatient clinic visit. An episode of AF is defined as an episode of at least 120 seconds duration.

Secondary outcome

Secondary outcomes include time to first documented AF, incidence of recurrent stroke or TIA and change of oral anticoagulation regimen. Progression of the length and incidence of atrial fibrillation episodes.

Study description

Background summary

Recent studies demonstrated that prolonged rhythm observation increases the detection of atrial fibrillation in patients prior diagnosed as cryptogenic stroke. Detection of atrial fibrillation in these patients has important therapeutic implications for the anticoagulation regimen. However, data on optimal monitoring duration and method of AF detection are limited.

Study objective

To establish evidence on the effectiveness of long term rhythm observation using an implantable loop recorder for detecting atrial fibrillation in patients with cryptogenic stroke.

Study design

Extended rhythm observation for atrial fibrillation is a prospective single center study with invasive measurements.

Study burden and risks

Using only a routine intervention will have minimal extra risk, burden for the patients will be slightly increased due to the nature of an implantable loop recorder. The device will be implanted under local anesthesia requiring a 2 cm incision to place the device subcutaneously.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients > 18 years of age
Recent episode (<=60 days) of cryptogenic ischemic stroke
Undetermined etiology with negative evaluation (including cardioembolism work-up) according to the TOAST criteria
Implantation of an implantable loop recorder within two months after index event
Able of providing informed consent

Exclusion criteria

Pre-existing indication for vitamin K antagonist
Untreated hyperthyroidism
Indication for pacemaker implantation, ICD or CRT device
Severe co-morbidity not likely to complete follow-up for one year

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2012
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Reveal® XT subcutaneous cardiac monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-07-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	19-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	15-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36491.044.11