Presence of Sub-Clinical Atrial Fibrillation using an implantable cardiac monitor in patients with cardiovascular risk factors (ASSERT II)

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To determine the rate of detection of sub-clinical atrial AF (* 5 minutes) within an average of 12 months following implant of the Confirm® Implantable Cardiac Monitor in patients with known cardiovascular risk factors and left atrial enlargement,...

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

Summary

ID

NL-OMON41317

Source
ToetsingOnline

Brief title
ASSERT II

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, palpitations

Research involving
Human

Sponsors and support

Primary sponsor: Population Health Research Institute of Hamilton Health Sciences

Source(s) of monetary or material Support: PHRI

Intervention

Keyword: cardiovascular risk factors, implantable cardiac monitor, sub-clinical Atrium Fibrillation

Outcome measures

Primary outcome

Number of patients with AF episodes longer than 5 minutes.

Secondary outcome

To determine the relationship between left atrial volume (continuous variable)

and the presence of AF.

To evaluate potential predictors/markers of sub-acute AF including: troponin-T,

NT-pro-BNP as well as echocardiographic parameters.

A preliminary economic analysis of screening this patient population with an

Implantable Cardiac Monitor.

Study description

Background summary

In a quarter of cases of ischemic stroke the cause is unknown. Sub-clinical AF might possibly play an important role in the origin of these strokes. The ASSERT study has shown that 85% of atrial tachyarrhythmias in pacemaker patients are without symptoms, and 10 - 40% of these patients have sub-clinical AF depending on the follow up period after implantation of the pacemaker. The question is how often patients without a pacemaker but with risk factors for cadiovascular events such as hypertension and diabetes have sub-clinical AF. Using an implantable cardiac monitor the heart rythm of patients can be monitored continuosly in a relatively minimal invasive way, and the incidence of sub-clinical AF can be determined in patients with cardiovascular risk factors. This makes it possible to treat patients with sub-clinical AF prophylactic if necessary.

Study objective

To determine the rate of detection of sub-clinical atrial AF (* 5 minutes) within an average of 12 months following implant of the Confirm® Implantable Cardiac Monitor in patients with known cardiovascular risk factors and left atrial enlargement, but without prior AF.

Study design

International, multicenter, observational cohort study.

Study burden and risks

Implantation of the cardiac monitor is an extra burden for the patient, but it is a relatively minimal invasive procedure. Prophylactic antibiotics will be administered, but there is always an infection risk. If this happens the device will have to be explanted.

At all follow up visits 1, 3, 6, 9 and 18 months after implantation the device will be read out. This does not give a physical burden for the patient but the patient will have to come to the out patient clinic.

Contacts

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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 will be eligible for inclusion if they provide written consent and meet both of the following:
1. Age * 65, plus:
a. CHA2DS2-VASc score * 2
Or
b. Obstructive sleep apnea (documented by polysomnography, ambulatory oximetry, positive Berlin Questionnaire or requiring the use of CPAP/BiPAP)
Or
c. BMI > 30;AND;2. Echocardiographic or biochemical evidence of increased risk of AF:
a. Left atrial enlargement on a clinical echocardiograph at any time prior to enrolment (defined as LA volume * 58 ml or LA diameter of * 4.4 cm)
Or
b. Serum NT-ProBNP * 290 pg/mL

Exclusion criteria

1. Previously documented history of atrial fibrillation or atrial flutter, with an episode duration of at least 5 minutes
2. Current chronic treatment with oral anticoagulation (i.e., those on peri-operative prophylaxis would be eligible)
3. Patient with existing implanted pacemaker or defibrillator
4. Definitive plan for cardiac surgery in the next 6 months (patients who are having coronary angiography with a possibility of cardiac surgery are still eligible)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2013
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Implantable cardiac monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-12-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	06-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	28-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	19-02-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-02-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	18-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL41674.098.12