Echocardiographic evaluation of left atrium flow patterns in relation to atrial fibillation and stroke

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This study has three objectives:1. To describe flow patterns in the left atrium in patient with sinus rhythm and atrial fibrillation. 2. To prospectively verify the data in patients with atrial fibrillation3. Correlation of abnormal flow patterns to...

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

Summary

ID

NL-OMON37334

Source
ToetsingOnline

Brief title
Left atrial flowpatterns

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
supraventricular tachycardia/heart rhytm disorders

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: geen externe geldstroom. Er wordt gebruik

gemaakt van de materialen van het HAGA ziekenhuis

Intervention

Keyword: Atrial fibrillation, Flow patterns, Stroke

Outcome measures

Primary outcome

Flow patterns in the left atrium in different patient groups.

Secondary outcome

Not applicable

Study description

Background summary

Atrial fibrillation (AF) is a risk factor for the occurrence of embolism leading to stroke. Stroke is associated with an increase in medical cost and high mortality and morbidity. Estimating the risk of stroke can be challenging. The choice of medication, antiplatelet therapy or vitamin K antagonists is very important. The prior is used in cases of low risk of embolism and has not many side effects. The latter is used in patients with high risk of embolism and has serious side effects.
At this moment the medication choice is based on clinical risk factors as described in the CHA2DS2-VASc score. This study tries to individualize the use of anticoagulants and thereby prevent major side effects.

Echocardiography can supply data to make a better choice for the type of anticoagulants. It is known that an abnormal flow pattern in the left ventricle can predict thrombus formation in the apex. There is little information about flow patterns in the left atrium. However in individual patients we have seen abnormal flow patterns.

The hypothesis of this study is that just like in the left ventricle, an abnormal flow pattern of the left atrium can predict thrombus formation in both the left atrium and left atrial appendix.

Study objective

This study has three objectives:

1. To describe flow patterns in the left atrium in patient with sinus rhythm and atrial fibrillation.
2. To prospectively verify the data in patients with atrial fibrillation
3. Correlation of abnormal flow patterns to stroke

Study design

A mono-center prospective, cross section, observational follow-up study. Study duration has been defined as a maximum of five years follow-up. In this study the patient is its own control.

Study burden and risks

The patients will undergo a transesofageal echo. For patient in group 1 and 3 this is standard medical care. For the patients in group 2 TEE will be performed before and after electrocardioversion. These patiënts are sedated. The TEE will elongate the duration of anaesthesia with an estimed 5-10 minutes. For the groups 3 and 4 an extra TEE will be performed. During TEE some throat discomfort and dyspnea can be experienced. During TEE there is ECG monitoring. ECG-stickers can cause allergic reactions. Patients should be sober for at least 6 hours.

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

Age range from 18 to 80 years
At least one documented episode of atrial fibrillation
Able to give informed consent
No contra-indications for trans esophegeal ultrasound examination
No contra-indication for cardioversion
No contra-indication for pulmonary vein isolation or mini-MAZE

Exclusion criteria

Unable to give informed consent
Prior myocardial infarction
Life expectation * 1 year
left ventricular dysfunction
Medical history of stroke or embolisation
Left ventricular thrombus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2012
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL39691.098.12