Diagnostic measure of atrial fibrillation on patients at outpatient TIA-clinic

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Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON34100

Source
ToetsingOnline

Brief title
TIA-AF-project

Condition

- Cardiac arrhythmias
- Central nervous system vascular disorders

Synonym
atrial fibrillation and ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Geen externe financiëring

Intervention

Keyword: atrial fibrillation, CVA, diagnostic measure, TIA

Outcome measures

Primary outcome

Primary study parameters:

- signs and symptoms fitting with atrial fibrillation (palpitations, short of

breath, dizziness or chest pain)

- left atrial enlargment at ECG

- left ventriclehypertrophy at ECG

- premature atrial heatbeats at ECG (with heartbeat > 70 bpm)

- hyperthyreodie

- cerebral ischemia in several flow areas

Outcome:

- atrial fibrillation

Secondary outcome

no applied to

Study description

Background summary

Atrial fibrillation (AF) predomintly occurs at later age and is associated with a higher chance of cardioembolic stroke or Transient Ischemic Attack (TIA). Each year, more than 45.000 people have a stroke or TIA in the Netherlands. Twenty-four percent of patients with ischaemic stroke (CVA or TIA) have atrial fibrillation. A stroke can have serious consequences for the patient and his environment. Within this group of patients, twenty-five percent die within one

month of the attack. This occurs frequently due to a cardiovascular disorder. Nineteen percent of all patients who have a stroke experience severe constraints in their daily activity.

The expectation is the prevelation of AF will increase the following years, due to the (double) aggiing of the population, and more patients survive a former fatal heartdisease. This last group of patients often develops complications like AF.

AF can present permanent (persistent or permanent atrial fibrillation) or present in episodes (paroxysmal atrial fibrillation). There is no difference in risk of an ischaemic stroke between the several types of atrial fibrillation. AF leads to an irregular heartbeat that often is under diagnosed. AF can only be diagnosed at the time of appearance by registration of the heartrythm via an electrocardiography (ECG) or holterregistration. Paroxysmal atrial fibrillation is therefore often missed and underdiagnosed.

According to the current guidelines (CHADS2-score) patients with stroke or TIA recieve vitamin-K-antagonists (such as acenocoumarol). If the diagnose AF is missed, this group of patients will have an increased chance of a relapse stroke or TIA. The ischaemic attack in patients with AF is in generally more severe than patients without AF. This is probably because of the size of the embolism of the left atrial. This underlines the importance of diagnostic measure of AF.

Recent analysis of the practice and literature have identified that long term registration of heartrythm is essential in diagnostic measure of paroxysmal atrial fibrillation. In patients with stroke or TIA ánd AF, left ventricle hypertrophy, left atrial enlargement, premature atrial heartbeats with a frequency of greater than 70 beats per minute is diagnosed. Beside that, AF occurs in patients with stroke or TIA and with cerebral ischemia in several flow areas, with hyperthyroid and in patients with signs and symptoms fitting with AF like palpitations, short of breath, dizziness and chest pain.

(see also page 3 and 4 of the study-protocol)

Study objective

The objective of this study is to optimize the diagnostic strategy of atrial fibrillation in patients with stroke or TIA. There is no evidence-based guideline to diagnose AF in patients who have had a stroke or TIA.
An objevtive related to this study is to reduce the probability of a relapse CVA or TIA.

The definition of this problem is: "Can paroxysmal atrial fibrillation be found in patients with signs and symptoms (fitting with atrial fibrillation), left atrial enlargement at ECG, left ventricle hypertrophy at ECG, premature

heartbeats at ECG (with a heartbeat more than 70 beats per minute), hyperthyroid and cerebral ischemia in several flow areas?"
We will study patients who survive an ischaemic stroke or TIA, seen at the outpatient TIA-clinic, by which at least one of the possible signs occurs (identified in literature)

(see also page 4 and 5 of the study-protocol)

Study design

The TIA-AF-project is defined diagnostic study at the diagnosis atrial fibrillation. It is a cross-sectional design by which the diagnosis atrial fibrillation is determined by a cardiologist
The patients will be included by the TIA-AF-flowchart (see annex 1 of the study-protocol).
Patients with AF in history and patients with AF on ECG at outpatient TIA-clinic will be excluded.
The methodology of diagnostic measure is the golden standard 'rapid-access cardio-AF', by which is used a 7-days holterregistration in stead of a 24-hours holterregistration.

Study burden and risks

Currently patients are referred to the cardiologist to diagnose a cardio-embolic-source. The patient recieves diagnostic examinations (ECG, 24-hours-holter and cardio-multiple-image) and an interview to discuss the results on several visits (in several days). In this study we will make use of the outpatient rapid access cardio-AF-clinic, by which patients recieve several examinations with an interview to discuss the results within the same day. This will probably be less aggravating for the patient (one visit in stead of several visits).

In this study we will use a 7-days-holterregistration instead of a 24-hours holterregistration. The 7-days-holterregistration is considered to be more aggravating for the patient. The riks associated with using a 7-days holter are small or non-existent. During the holterregistration the patient cannot take a shower; however the patient can switch the holter off before taking a shower and switch it back on the holter after the shower.

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

Ischemic stroke (CVA or TIA)
signs and symptoms of atrial fibrillation
left atrial enlargement at ECG
left ventricle hypertrophy at ECG
premature atrial complex at ECG
hyperthyreoidie
ischemic attacks in several cerebral flow area

Exclusion criteria

atrial fibrillation in history
atrial fibrillation registrated at ECG at outpatient clinic neurologie-TIA
hemorragic CVA

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	27-12-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL34192.100.10