

Diagnostic of atrial fibrillation on patients at TIA-clinic

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To identify that physical complaints fitting with atrial fibrillation, hyperthyroidie, left atrial enlargement at ECG, left ventricle hypertrophy at ECG, premature atrial complex (with heartbeat > 70 bpm) at ECG and cerebral ischemic attacks in...

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

Summary

ID

NL-OMON34477

Source

ToetsingOnline

Brief title

TIA-AF-project

Condition

- Cardiac arrhythmias
- Central nervous system vascular disorders

Synonym

atrial fibrillation

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, CVA, diagnostic, TIA

Outcome measures

Primary outcome

Physical complaints of atrial fibrillation (palpitations, short of breath, dizziness, or chest pain)

Left atrial enlargement at ECG

Left ventricle hypertrophy at ECG

Premature atrial complex at ECG (with heartbeats of > 70 bpm)

Hyperthyroidism (TSH < 0.35 mU/l and free T4 > 24.0 pmol/l at serum)

Ischaemic attacks at several cerebral flow areas (detected at CT-scan)

Outcome:

Atrial fibrillation

Secondary outcome

not applied to

Study description

Background summary

Atrial fibrillation (AF) occurs mainly at higher age and is attended with a higher chance of cardioembolic Cerebro Vascular Accident (CVA) or Transient Ischaemic Attack (TIA). In the Netherlands more than 45,000 people annually get a CVA or TIA, with radical consequences for the patient and his environment. Of this group of patients 25% die within a month, mostly because of a cardiovascular disorder and 19% experience severe constraints in daily activity.

They expect the prevalence of AF will increase in the next following years, on

the one hand because of the (double) ageing of the population, on the other hand because more patients survive a former fatal heart disease. This last group of patients develop 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 what is often underdiagnosed. AF can only be diagnosed at the time of appearance by registration of the heart rhythm via an electrocardiogram (ECG) or Holter registration. Paroxysmal atrial fibrillation is therefore often underdiagnosed.

Patients with CVA or TIA and AF receive according to the current guidelines (CHADS₂-score) vitamin-K-antagonists (like acenocoumarol). As the diagnosis will be missed, this group of patients, will have an increased chance of a relapse CVA or TIA. The ischaemic attack in patients with AF is in general more severe than in patients without AF, probably because of the size of the embolism of the left atrium. That's why correct diagnosis of AF in patients with CVA or TIA is important.

Analysis of practice and literature have identified that long term registration of heart rhythm is essential in diagnosis of mainly paroxysmal atrial fibrillation. AF occurs in patients with CVA or TIA with left ventricle hypertrophy, with left atrial enlargement, premature heartbeats with a frequency of > 70 beats per minute. Besides that, AF occurs in patients with CVA or TIA with cerebral ischemia in several flow area, with hyperthyroidism and in patients with signs and symptoms like palpitations, short of breath, dizziness and chest pain.

Study objective

To identify that physical complaints fitting with atrial fibrillation, hyperthyroidism, left atrial enlargement at ECG, left ventricular hypertrophy at ECG, premature atrial complex (with heartbeat > 70 bpm) at ECG and cerebral ischemic attacks in several flow area are independent predictors of atrial fibrillation.

Besides, to offer a correct diagnostic procedure of atrial fibrillation, so that, after adjusting medication, the chance of a relapse CVA or TIA will be decreased.

Study design

The TIA-AF-project is a 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.

Study burden and risks

The patient will be directed to the outpatient clinic cardiology for diagnostic: fast-diagnostic-clinic (rapid access) atrial fibrillation. This care is existing. What in this study will be used, is a 7-days holterregistration instead of a 24-hours holterregistration. A 7-days holterregistration is no common care, though is already used if the cardiologist suspect atrial fibrillation, but is not (yet) detected at a 24-hours holterregistration.

The 7-days holterregistration is more aggravating for the patient than a 24-hours holterregistration, but the strain is light and has no or slight risks. During the holterregistration the patient can not take a shower; but the patient can switch off and on the holter by himself, if the patient likes to take a shower.

The patient will be directed to the outpatient clinic cardiology for fast-diagnostic, at which the patient in one day receive all diagnostic medical examinations and results. Before starting this project the patient was directed to the cardiologist (at suspicion of a cardiac embolic source), by which the patient had to go to outpatient clinic several times for diagnostic medical examinations and results. In this project the patient will be aggravated less.

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 CVA or TIA

signs and symptoms of atrial fibrillation

left atrial enlargement at ECG

left ventricle hypertrophy at ECG

premature atrial complex at ECG

hyperthyreodie

ischemic attacks in several cerebral flow area

Exclusion criteria

Atrial fibrillation in history

Atrial fibrillation diagnosed at ECG

hemorrhagic 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: 10-09-2010

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	NL32829.100.10