Detecting and Diagnosing Atrial Fibrillation: enhanced case-finding in patients from general practice and evaluating three ways of irregular pulse detection. A cluster randomised trial with nested diagnostic studies

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The study has two main objectives. The first objective is to estimate the extra yield in detected cases of AF in patients aged 65 years and over, using case finding. The second is to compare three methods to detect AF.

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

Summary

ID

NL-OMON45031

Source
ToetsingOnline

Brief title
Detecting and Diagnosing Atrial Fibrillation (D2AF)

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
arrhythmia, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Applied Biomedical Systems BV (MyDiagnostick),Microlife/Retomed (WatchBP Home A)

Intervention

Keyword: Atrial Fibrillation, Diagnosis, Electrocardiography, Primary Health Care

Outcome measures

Primary outcome

We have two primary outcomes. Firstly, we determine the difference in the number of patients with newly found AF in intervention and control practices. Secondly, we calculate sensitivity and specificity of pulse palpation, eBPM-AF and hand-ECG with the 12-lead ECG as reference standard.

Secondary outcome

In addition to our primary objectives, our study will address the following points. We will:

* investigate the diagnostic test characteristics of the hand-ECG device for home monitoring, using the two week Holter as a reference standard.

* investigate the number of patients with a regular pulse with all index tests negative for AF, in whom the two week Holter shows (paroxysmal) AF.

* provide real-practice data on current pathways for AF detection in Dutch general practice (process evaluation control practices), disclosing divergence from current guidelines.

* establish current AF prevalence and incidence figures in Dutch general

practice.

* provide patient profiles of newly detected patients with AF, including

patients with *silent* paroxysmal AF. We will also explore the differences

between patients with AF of Caucasian and non-Caucasian origin.

* develop a prediction model for finding (different types of) AF.

* determine the quality of life in patients with asymptomatic AF.

Study description

Background summary

Atrial fibrillation (AF) is an irregular heart rhythm in which electrical signals are generated chaotically within the atria of the heart instead of the sinus node. This causes changes in atrial blood flow, increasing the chance of thrombus formation. The prevalence of AF is over 3.5% in people aged over 65 years. AF has important medical implications: increased mortality, reduced quality of life and increased risk of heart failure and stroke. Adequate antithrombotic treatment decreases the risk of stroke and death. The costs of care for stroke rank in the top ten of most expensive diseases and comprise over 2.2 to 4.4% of total health care costs in the Netherlands. AF is often asymptomatic and therefore often first discovered when stroke has already occurred. Early identification of AF could thus prevent many of these serious and costly events.

Study objective

The study has two main objectives. The first objective is to estimate the extra yield in detected cases of AF in patients aged 65 years and over, using case finding. The second is to compare three methods to detect AF.

Study design

Cluster-randomized trial and nested cross-sectional diagnostic studies with randomization at the practice level. Study duration is one year.

Intervention

In the intervention practices we perform optimized case finding. Marked patients who visit the practice will undergo the three index tests. These tests

are pulse palpation, electronic sphygmomanometer with AF-detection (eBPM-AF) and handheld electrocardiogram (hand-ECG). The reference standard is the conventional 12-lead ECG. In case of a negative reading two week Holter recording is performed to detect paroxysmal atrial fibrillation. Patients taking home the Holter will also perform measurements with the hand-ECG at home, three times a day. In control practices care *as usual* is delivered.

Study burden and risks

There are no risks associated with participation. In intervention practices the burden consists of the time investment of undergoing the index and reference tests. In all patients the pulse will be palpated and eBPM-AF and hand-ECG will be performed. In a sample of patients a 12-lead ECG will be performed and these patients will be asked to take a Holter recorder and a hand-ECG home for two weeks. The Holter recorder can provoke discomfort. In control practices there are no burdens or risks associated with participation.

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

Aged 65 and over
Not diagnosed with atrial fibrillation

Exclusion criteria

Legal incompetence
Pacemaker
Not capable of visiting the general practice

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2015
Enrollment:	19200
Type:	Actual

Medical products/devices used

Generic name:	MyDiagnostick
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL48215.018.14