RAPID-AF: a novel method to detect paroxysmal atrial fibrillation in primary care and post-stroke patients with no history of AF.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28464

Source
Nationaal Trial Register

Brief title
RAPID-AF

Health condition

Atrial fibrillation (NL: boezemfibrilleren); paroxysmal atrial fibrillation (NL: paroxismaal boezemfibrilleren); ischemic stroke (NL: herseninfarct, beroerte); transient ischemic attack (TIA) (NL: TIA).

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam, Afdeling Huisartsgeneeskunde, Meibergdreef 15, 1105 AZ, Amsterdam, The Netherlands.
Source(s) of monetary or material Support: ZonMW, The Netherlands Organization for Health Research and Development, grant No. 80-83910-98-13046; Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

The diagnostic test characteristics of the SRA algorithm of the first 1, 2, 6, 12 and 24 hours of the Holter monitoring (sensitivity, specificity, positive and negative predictive value) for detecting pAF in both primary care patients and post-stroke patients with two weeks continuous Holter monitoring as reference standard for each patient group as well as for the complete cohort.

Secondary outcome

- Incidence of AF after 24 hours, 48 hours, 72 hours, one week and two weeks of continuous Holter monitoring in both primary care and post-stroke patients.

- A prediction model for pAF including SRA results and patient variables in both primary care and post-stroke patients.

- Patient satisfaction for wearing the 14-day Holter monitor.

Study description

Background summary

Atrial fibrillation (AF) increases the risk of stroke more than 5 times. With an increasing incidence with age, AF is recognized as a major public health burden in the Western population. Since stroke risk can be effectively reduced by medication once AF has been diagnosed, early detection of the arrhythmia is warranted. Detection of AF, however, is complicated by its often paroxysmal (pAF) and asymptomatic nature. Effective pAF detection therefore requires multiple-day continuous heart rhythm (Holter) monitoring in high risk groups. This is a major burden on patients.

Previous studies with the Stroke Risk Analysis (SRA) algorithm, which assesses pAF risk from electrocardiographic anomalies in short (1-24h) snippets of Holter data, have shown that the algorithm is able to predict with reasonable sensitivity and specificity the outcome of multiple-day Holter monitoring. The RAPID-AF study will be the first study to perform a large-scale validation of the SRA algorithm in both primary care and post-stroke patients.

When sufficiently validated, the SRA algorithm could serve as a triage test for further Holter monitoring. The SRA algorithm thus has potential to reduce screening burden to several hours in those patients who score ‘low risk of pAF’, where they would otherwise have had to undergo a complete 14-day Holter.

Study objective

Stroke Risk Analysis (SRA) (Apoplex Medical, Pirmasens, Germany) is a Holter based algorithm that assesses the risk of underlying paroxysmal atrial fibrillation (pAF) from electrocardiographic anomalies in 1-24h snippets of Holter data while the patient is still in sinus rhythm, with two weeks continuous Holter monitoring as reference standard.

We expect that SRA has both sufficient negative predictive power (sensitivity) to select patients who don’t need any further evaluation for AF and sufficient positive predictive power (specificity) to select patients who are eligible for further long term ECG monitoring.

Study design

- Day 0: start of continuous Holter monitoring;

- Day 14: end of Holter monitoring; assessment of diagnosis 'pAF yes or no' from Holter monitoring and relaying outcome to treating physician (neurologist in AMC cohort, general practitioner in D2AF cohort);

- Day 14+: performing SRA algorithm on snippets of first 1, 2, 6, 12 & 24h of 14-day recording (blinded to the final outcome of the 14-day recording, i.e. the reference standard); assessment of patient satisfaction through questionnaire.

Intervention

- All included patients undergo 14-day continuous Holter monitoring, either as standard of care after ischemic stroke or TIA (post-stroke cohort) or as per inclusion into the intervention arm of the D2AF study (primary care cohort).

- We perform the SRA algorithm on snippets of the first 1, 2, 6, 12 and 24 hours of the 14-day continuous Holter monitoring. For each snippet, the algorithm provides an outcome expressed as either of 3 categories: (1) sinus rhythm (SR) with low risk of pAF; (2) SR with high risk of pAF, and; (3) present AF.

- We compare the outcome of the SRA algorithm with the reference standard, i.e. the final outcome of conventional 14-day continuous Holter monitoring.

- We assess patient satisfaction with undergoing 14-day Holter by means of a questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

The RAPID-AF study will be performed in two separate cohorts:

(1) consecutive patients presented to the stroke unit of the department of Neurology of the Academic Medical Center (AMC), Amsterdam, and;

(2) primary care patients enrolled in the intervention arm of the Detecting and Diagnosing Atrial Fibrillation (D2AF) study, a cluster randomized AF screening trial in 96 General Practices in The Netherlands (NTR No. NTR4914; ZonMw No. 839110006; METC AMC No. 2014_236).

Inclusion criteria for the AMC (post-stroke) cohort:

- Clinical diagnosis of ischemic stroke or TIA (acute neurological deficit with no sign of tumor or primary cerebral haemorrhage on CT-cerebrum, symptoms lasting >24h resp. <24h)

- Age > 18 years

- Capable of wearing 14-day Holter

- Consent (written, or oral and subsequently noted in electronic health record by treating physician) for use of care data for study

Inclusion criteria for the D2AF (primary care) cohort:

- Age > 65 years

- Family practice attendance during study period (1 year)

- Written informed consent for inclusion into intervention arm of D2AF-study

Exclusion criteria

AMC cohort:

- History of atrial fibrillation (AF)

- AF on admission ECG

- Pacemaker and/or ICD in situ

- Known life long indication for oral anticoagulants or LMWH

- Life expectancy <1 year

- Other probable explanation for cerebral ischemia (e.g. periprocedural ischemic stroke, carotid artery dissection) for which cardiac monitoring is not indicated

D2AF cohort:

- Legal incompetence or inability to provide written informed consent

- History of AF

- Suffering from terminal illness

- Pacemaker and/or ICD

Study design

Design

Study type: Observational non invasive

Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2017
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-03-2017
Application type:	First submission

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
NTR-new	NL6314
NTR-old	NTR6489
Other	AMC METC No. W16_168 : ZonMw No. 80-83910-98-13046

Study results