Het afstemmen van het risico op beroerte en op bloeding door gebruik van CHA2DS2-VASc bij behandeling van patiënten met Atrium Fibrilleren in de eerste lijn.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21810

Source
NTR

Brief title
CAFe

Health condition

Atrial fibrillation
Ischaemic Stroke
CHA2DS2-VASc
Clinical Prediction Rule

Atriumfibrilleren
Boezemfibrilleren
Beroerte
Ischaemisch CVA
Klinische beslisregel

Sponsors and support

Primary sponsor: Julius Centrum for Health Sciences and Primary Care UMC Utrecht
P.O. Box 85500
3508 GA Utrecht
Phone: 088-75 68 181
Source(s) of monetary or material Support: ZORRO

Intervention

Outcome measures

Primary outcome

Primary endpoint is ischaemic stroke within two years. The possible ischaemic stroke cases that occur within the two year follow up period will all be confirmed at the end of the study by an independent adjudication committee based on all available information from the (anonymous) patient files, including letters from specialists with results from CT and/or MRI scans and information on neurological testing.

Secondary outcome

This study has several secondary endpoints:

1. Transient ischaemic attacks in two years – defined as a transient episode of neurologic dysfunction caused by focal brain, spinal cord, or retinal ischemia, however, without cerebral infarction (no defect on CT brain) –, confirmed by an independent adjudication committee;

2. All (major and non-major) bleeding events in two years – defined by bleedings causing a fall in haemoglobin level of ≥1.24 mmol/L, or d) bleeding that require transfusion of two or more units of packed red blood cells 37 – measured by ICPC codes and specialists' letters;

3. Conform previous studies in this field, a composite secondary endpoint of major adverse cardiac events (MACE, consisting of cardiovascular death, myocardial infarction, coronary revascularization (PCI, CABG) and cardiovascular hospitalization) within two years is also measured per patient;

4. Guideline adherence, calculated as the proportion of AF patients for each primary care physician that is threated according to the CHA2DS2-VASc score in the current international guidelines.

Study description

Background summary

Rationale:

Atrial fibrillation (AF) is the most common cardiac arrhythmia with a prevalence of 1-2% in the general population, increasing with age. It is associated with a 5-fold increased risk of stroke if untreated. While anticoagulant agents are effective in preventing stroke, physicians in daily practice must balance their benefit against potential bleeding complications when considering therapy in every singly AF patient.

Guidelines recommend anticoagulation treatment based on the patients' stroke risk, as assessed by scoring a clinical prediction rule (CPR) of which CHA2DS2-VASc nowadays is considered to be the best. Importantly, this CPR has also been evaluated in a primary care population, showing to have good predictions. This in turn leads to both optimized and individualized anticoagulant treatment decisions: anticoagulation if the anticipated stroke risk is high and no anticoagulation (or only aspirin) if stroke risk is low. However, research has proved that adherence to these guidelines is low and patients sometimes are overtreated and frequently undertreated, especially in primary care. Because 50% or over of all AF patients are managed in primary care, application of the aforementioned prediction rule could improve anticoagulant treatment and thus optimize the balance between stroke reduction and bleeding risk in individual patients with AF.

Objective:

To improve optimal evidence-based anticoagulant treatment in patients with AF in primary care.

Study design:

Cluster randomized study with 2 years of follow-up.

Study population:

38 Dutch primary care physicians and their patients with atrial fibrillation enlisted in the electronic patient registry.

Intervention and Control group:

In participating primary care practices, all patients with an (ECG confirmed) diagnosis of AF will (anonymously) be identified from the electronic patient registry. Subsequently, the individual patient's score on the CHA2DS2-VASc CPR will be calculated, and potential contra-indications to anticoagulant treatment assessed. In practices randomized to the index group, the aforementioned information will be provided to the primary care physician in combination with a clear treatment recommendation based on the score and on contra-indications. This is all according to the most recent international guidelines on atrial fibrillation form the European Society of Cardiology. Participating physicians in the index group will be asked to discuss these anticoagulation treatment recommendations with their patients (shared decision), and – if needed – change treatment accordingly (though they are allowed to overrule the recommendations based on individual patient or physician preferences, if necessary). In the control group, the primary care physicians receive a list of patients with atrial fibrillation and will be asked to check whether these patients do have ECG-confirmed AF. They do not receive a CPR score, contraindications or treatment recommendations from the researchers. Instead, these physicians are asked to apply care-as-usual.

Main study parameters/endpoints:

The primary outcome is the number of ischaemic strokes. Secondary outcomes are: 1) number of transient ischaemic attacks, 2) major bleeding events, 3) major adverse cardiac events (MACE), and, 4) guideline adherence (quantified as the proportion of patients that are treated in accordance to the most recent ESC current guidelines on atrial fibrillation).

Nature and extend of the burden and risks associated with participation, benefit and group relatedness:

Optimizing treatment according to current ESC guidelines – that is the CHA2DS2-VASc score – is the only burden associated with participation for both primary care physicians and (future) AF patients. The benefit for the patients will be an anticipated reduction in stroke risk that will greatly outweigh the burden of bleeding risk.

Study objective

Atrial fibrillation (AF) is the most common cardiac arrhythmia with a prevalence of 1-2% in the general population, increasing with age. It is associated with a 5-fold increased risk of stroke if untreated. While anticoagulant agents are effective in preventing stroke, physicians in daily practice must balance their benefit against potential bleeding complications when considering therapy in every singly AF patient.

Guidelines recommend anticoagulation treatment based on the patients' stroke risk, as assessed by scoring a clinical prediction rule (CPR) of which CHA2DS2-VASc nowadays is considered to be the best. Importantly, this CPR has also been evaluated in a primary care population, showing to have good predictions. This in turn leads to both optimized and

individualized anticoagulant treatment decisions: anticoagulation if the anticipated stroke risk is high and no anticoagulation (or only aspirin) if stroke risk is low. However, research has proved that adherence to these guidelines is low and patients sometimes are overtreated and frequently undertreated, especially in primary care. Because 50% or over of all AF patients are managed in primary care, application of the aforementioned prediction rule could improve anticoagulant treatment and thus optimize the balance between stroke reduction and bleeding risk in individual patients with AF.
Therefore, the objective of this cluster randomized trial is to improve optimal evidence-based anticoagulant treatment in patients with AF in primary care.

Study design

Measurements will be performed at baseline and after two years follow-up.

Intervention

For all consented and randomized primary care physicians, encoded information on all their AF patients will be extracted from the registry using an automated search within an already existing research network “Julius Huisartsen Netwerk”.) In the index group, for each AF patient the CHA2DS2-VASc score as well as the related treatment indication per score (see section 2) and possible contra-indications for anticoagulant treatment will be provided. Physicians are allowed to overrule the recommendation at all times.

In the control group, no CHA2DS2-VASc score, treatment indication, or contraindication of the AF patients will provided.

Contacts

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Eligibility criteria

Inclusion criteria

Primary care physicians affiliated with the 'Julius Huisartsen Netwerk' (JHN).

Exclusion criteria

All physicians are eligible to participate, no exclusion criteria apply.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	38
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-12-2012
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	NL3583
NTR-old	NTR3741
Other	METc Universitair Medisch Centrum Utrecht : 12-505/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A