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.

Gepubliceerd: 06-12-2012 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21810

Bron
NTR

Verkorte titel
CAFe

Aandoening

Atrial fibrillation
Ischaemic Stroke
CHA2DS2-VASc
Clinical Prediction Rule

Atriumfibrilleren
Boezemfibrilleren
Beroerte
Ischaemisch CVA
Klinische beslisregel

Ondersteuning

Primaire sponsor: Julius Centrum for Health Sciences and Primary Care UMC Utrecht
P.O. Box 85500
3508 GA Utrecht
Phone: 088-75 68 181
Overige ondersteuning: ZORRO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3583

Register	ID
NTR-old	NTR3741
Ander register	METc Universitair Medisch Centrum Utrecht : 12-505/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A