Integrated management of the heart rhythm disorder atrial fibrillation, including stroke prevention with blood thinners and care for comorbidities, by the practice nurse and general practitioner in primary care

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23738

Bron
Nationaal Trial Register

Verkorte titel
ALL-IN

Aandoening

Atrial fibrillation, anticoagulation, comorbidity, integrated care, primary care.
Atriumfibrilleren, antistolling, comorbiditeit, integrale zorg, eerste lijn.

Ondersteuning

Primaire sponsor: Sponsor (verrichter) is the Isala hospital, Zwolle, the Netherlands. Performer (uitvoerder) is the Julius Center for Health Sciences and Primary Care of the University Medical Center Utrecht, The Netherlands.

Overige ondersteuning: Stichting Achmea Gezondheidszorg, Hein Hogerzeil Stichting and Roche Diagnostica Nederland.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

All-cause mortality

Toelichting onderzoek

Achtergrond van het onderzoek

Background & Aim: Atrial fibrillation (AF) is the most common cardiac arrhythmia with an increased risk of stroke and mortality. It often involves frail, elderly patients, requiring adequate care for comorbidities, lifestyle and tailored anticoagulation treatment. Given the expected increase in prevalence in the next couple of years, transition of care for AF patients from secondary care to primary care is desired. However, data on the safety and (cost)effectiveness are lacking. This study evaluates if integral management of patients with AF by the practice nurse and general practitioner, including care for comorbidities and anticoagulation, is non-inferior to usual care.

Method: The ALL-IN study is a cluster randomized trial performed in approximately 60 primary care practices in the region of Zwolle, The Netherlands, with more than 1000 AF patients aged 65 years or over. Patients from primary care practices randomized to the intervention arm will receive integral AF management, consisting of a) visits to the practice nurse three times a year and once yearly to the general practitioner, b) INR measurements performed by the practice nurse, and c) easy access consultation from secondary care through the establishment of an Expert Center for Anticoagulation and an Expert Center Cardiology. Patients from practices randomized to the control arm will receive care as usual by the Dutch Thrombosis Service, cardiologist and/or general practitioner.

Results: The study will start in 2016 with a follow-up time of 24 months. Primary endpoint is all-cause mortality. Secondary endpoints are cardiovascular mortality, (non)cardiovascular hospitalization, Major Adverse Cardiac Events (MACE), stroke, major bleeding, quality of life and cost-effectiveness.

Conclusions: The ALL-IN trial is the scientific evaluation of a health care innovation that – due to the delegation of tasks to the practice nurse and the establishment of the Expert Centers for Anticoagulation and Cardiology– aims for sustainable and accessible care, close to the AF patient.

Doel van het onderzoek

The hypothesis of this study is that integral AF management in primary care - including case-management for anticoagulation (stroke prevention) as well as appropriate attention given to all cardiac and non-cardiac comorbidities - is at least non-inferior and likely improves patient care in elderly AF patients, as compared to usual care.

Onderzoeksopzet

24 months.

Onderzoeksproduct en/of interventie

Patients from primary care practices randomized to the intervention arm will receive integral AF management, consisting of a) visits to the practice nurse three times a year and once yearly to the general practitioner, b) INR measurements performed by the practice nurse (for which the practice nurse will be trained), and c) easy access consultation from secondary care through the establishment of an Expert Center for Anticoagulation and an Expert Center Cardiology.

Patients from practices randomized to the control arm will receive care as usual by the Dutch Thrombosis Service, cardiologist and/or general practitioner.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participating primary care practices need to be willing and able to provide integral management to their AF patients.
Patients aged 65 years or over of participating practices with documented AF are eligible for participation if they do not meet any of the exclusion criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Unwillingness to provide informed consent by the participating general practitioners is the only exclusion criterion for primary care practices in this study.

Patients are not eligible for this study if
a) they have a life expectancy shorter than 3 months,

b) if their age at baseline is below 65 years,

c) if they have an Internal Cardioverter Defibrillator (ICD) or a Cardiac Resynchronisation Therapy (CRT) device,

d) if they had cardiac resynchronization treatment, cardiac ablation or cardiac surgery less than 3 months prior to inclusion or one of these procedures planned,

e) if they had heart valve surgery in the past or are known with a rheumatic mitral valve stenosis,

f) if they had pulmonary vein isolation (PVI) in the past or have a PVI planned,

g) if they are legally incapable of providing informed consent for the intervention program,

h) if they participate in another randomized trial on AF.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	29-01-2016
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44028
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5407
NTR-old	NTR5532
CCMO	NL53065.075.15
OMON	NL-OMON44028

Resultaten