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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23738

Source
Nationaal Trial Register

Brief title
ALL-IN

Health condition

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

Sponsors and support

Primary 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.
Source(s) of monetary or material Support: Stichting Achmea Gezondheidszorg, Hein Hogerzeil Stichting and Roche Diagnostica Nederland.

Intervention

Outcome measures

Primary outcome

All-cause mortality

Secondary outcome

Cardiovascular mortality, cardiovascular and non-cardiovascular hospitalization, Major Adverse Cardiac Events (MACE), stroke, major bleeding, quality of life and cost-effectiveness.

Study description

Background summary

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.

Study objective

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.

Study design

24 months.

Intervention

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.

Contacts

Public
Julius Center for Health Sciences and Primary Care, UMC Utrecht Str. 6.131
C.J. van den Dries
Postbus 85500

Utrecht 3508 GA
The Netherlands
+31 6 38365344
Scientific
Julius Center for Health Sciences and Primary Care, UMC Utrecht Str. 6.131
C.J. van den Dries
Postbus 85500

Utrecht 3508 GA
The Netherlands
+31 6 38365344

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2016
Enrollment:	1000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44028
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results