

# 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.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23738

### Source

NTR

### 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**

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### **Scientific**

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## 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**

NTR-new

NTR-old

CCMO

OMON

**ID**

NL5407

NTR5532

NL53065.075.15

NL-OMON44028

**Study results**