# Effects of VERApamil versus metoprolol to prevent progression from Paroxysmal to persistent Atrial Fibrillation

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We hypothesize that verapamil reduces progression from paroxysmal to persistent AF, improves rate control, exercise tolerance and quality of life and reduces costs compared to metoprolol.

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

# Summary

## ID

NL-OMON44431

**Source** ToetsingOnline

Brief title VERAPAF

## Condition

Cardiac arrhythmias

**Synonym** atrial fibrillation, atrial rhythm disorder

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Martini Ziekenhuis **Source(s) of monetary or material Support:** Door de Martini Academie;MZH Groningen,Medtronic B.V.,Unrestricted Research grants van Abbott

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### Intervention

Keyword: atrial fibrillation, metoprolol, progression, verapamil

### **Outcome measures**

#### **Primary outcome**

Primary outcome variable is incidence of AF progression from paroxysmal to

persistent AF or the need for PVI.

#### Secondary outcome

Main secondary outcome variables are AF burden, heart rate, exercise tolerance,

symptom severity, quality of life, and costs.

# **Study description**

#### **Background summary**

Paroxysmal (self-terminating) atrial fibrillation (AF) has the tendency to become persistent over time (non-self-terminating). Verapamil and metoprolol are both registered for rate-control in AF. Animal experimental and human data suggest that verapamil, but not betablockers, can reduce AF progression. Previous studies in patients with permanent AF suggest that verapamil exhibits better rate control, with better exercise tolerance and quality of life, compared to metoprolol.

#### **Study objective**

We hypothesize that verapamil reduces progression from paroxysmal to persistent AF, improves rate control, exercise tolerance and quality of life and reduces costs compared to metoprolol.

#### Study design

A multicentre, prospective, two-arm, open label, randomized controlled trial.

#### Intervention

Patients are randomized to verapamil slow release 240mg once daily or

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metoprolol slow release 100mg once daily. Dose adjustments (half or double) can be made upon the response to heart rate or blood pressure. In total 200 patients with paroxysmal AF will be included. Data will be collected at baseline, after 1 month, 6 months and 12 months.

#### Study burden and risks

Both verapamil and metoprolol are registered for rate control in AF and can be safely administered in the selected study population. Participating patients visit the hospital four times during one year instead of the usual once yearly visit. We expect an absolute risk reduction for AF progression of 15% in patients receiving verapamil versus metoprolol. This will also result in a lower hospitalization rate and fewer pulmonary vein isolations. Quality of life, side effects and exercise tolerance will be compared and cost-effectiveness of the treatments will be calculated.

# Contacts

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

In order to be eligible to participate in this trial, a subject must meet all of the following criteria:

Patients (age >= 18) with symptomatic paroxysmal AF with an indication for rate control medication who participate in the RACE 5 registry. Patients must be able and willing to sign informed consent for the randomised study.

## **Exclusion criteria**

Exclusion criteria are (history of) persistent AF, previous adverse effects to the study drugs, heart failure with reduced ejection fraction, symptomatic hypotension, atrioventricular conduction disturbance, severe asthma/COPD, history of pulmonary vein isolation (PVI), pregnancy and breastfeeding.

# Study design

## Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	200
Туре:	Anticipated

# **Ethics review**

Not approved Date: Application type: Review commission:

13-12-2018 First submission RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27565 Source: Nationaal Trial Register Title:

### In other registers

Register	ID
ССМО	NL62365.099.17
Other	protocol gaat aangemeld worden bij clinicaltrials.gov
OMON	NL-OMON27565