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

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

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

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
Type:	Anticipated

Ethics review

Not approved

Date:	13-12-2018
Application type:	First submission
Review commission:	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: NTR
Title:

In other registers

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