EN: Which drug prevents worsening of paroxysmal atrial fibrillation: verapamil or metoprolol?

NL: Welk medicijn voorkomt het hardnekkiger worden van paroxismaal atriumfibrilleren: verapamil of metoprolol?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27565

Source
NTR

Brief title
VERAPAF

Health condition

EN: atrial fibrillation, progression, verapamil, metoprolol

NL: atriumfibrilleren, progressie, verapamil, metoprolol

Sponsors and support

Primary sponsor: Martini ziekenhuis Groningen
Source(s) of monetary or material Support: Unrestricted research grants from Abbott and Medtrinic B.V.

Intervention

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

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

After inclusion and randomization, baseline assessments including history taking, physical examination, questionnaires (Toronto AF Severity Scale, EQ-5D-5L, sexual function (FSFI or IIEF), iMTA PCQ), transthoracic echocardiography including PA-tdi interval measurement, exercise test during sinus rhythm, and electrocardiogram (ECG) will be performed. Vagal or sympathetic induction of AF will be determined from clinical history.

Patients will be followed at 1 month, 6 months and 12 months after randomisation, and more often in case of persisting symptoms of AF.

After 1 month, findings from clinical history, physical examination and ECG will determine whether a dose adjustment is required. Dose may be halved or doubled. After 6 and 12 months of follow-up clinical history, physical examination, ECG and questionnaires will be obtained again. During the last follow-up visit, after 12 months of treatment, transthoracic

echocardiogram and exercise test will be repeated.

In all patients, remote monitoring recordings will be collected on a daily basis as part of their participation in the RACE 5 registry and evaluated every 3 months in order to assess AF burden and AF progression. Heart rate variability will also be measured to define the presence of vagal or adrenergic AF.

The occurrence of adverse events will be continuously assessed. After 12 months the trial will be finished. Patients will continue care as usual.

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.

Contacts

Public
R.G. Tieleman
Van Swietenplein 1

Groningen 9728 NT
The Netherlands
(+31) (0)50 - 524 5800
Scientific
R.G. Tieleman
Van Swietenplein 1

Groningen 9728 NT
The Netherlands
(+31) (0)50 - 524 5800

Eligibility criteria

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, contra-indication for the study drugs (i.e. 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44431
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6564
NTR-old	NTR6745
CCMO	NL62365.099.17
OMON	NL-OMON44431

Study results