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?

Gepubliceerd: 10-10-2017 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27565

Bron
Nationaal Trial Register

Verkorte titel
VERAPAF

Aandoening

EN: atrial fibrillation, progression, verapamil, metoprolol

NL: atriumfibrilleren, progressie, verapamil, metoprolol

Ondersteuning

Primaire sponsor: Martini ziekenhuis Groningen
Overige ondersteuning: Unrestricted research grants from Abbott and Medtrinic B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome variable is incidence of AF progression from paroxysmal to persistent AF or the need for PVI.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

R.G. Tieleman
Van Swietenplein 1

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

Wetenschappelijk

R.G. Tieleman
Van Swietenplein 1

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44431
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten