Enhanced sympathetic activity as a mechanism of Atrial Fibrillation

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Patients with new-onset or recurrent AF have an altered myocardial sympathetic activity. The quantification of sympathetic activity with 123I-mIBG scintigraphy, as well as its change over time after restoration of sinus rhythm, can be used to target...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22645

Bron
NTR

Verkorte titel
MAD-AF

Aandoening

Atrial fibrillation

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Documented recurrence of AF (or other atrial arrhythmias lasting longer than 30 seconds as per HRS/EHRA/ECAS consensus document definition) within the first 12 months after

cardioversion.
Documentation of recurrent AF includes, but is not limited to:
a) ECG documentation of AF recurrence
b) Read out of pacemaker or ICD demonstrating AF
c) Holter recordings demonstrating AF
d) Subsequent electrical or chemical cardioversion for any supraventricular arrhythmia

Toelichting onderzoek

Achtergrond van het onderzoek

We are poor in predicting, which individual patient suffering from atrial fibrillation(AF) benefits from rhythm control strategies. Cardioversion restores sinus rhythm, but does not prevent recurrence of AF. Hence, up to 70% of patients undergoing cardioversion have an arrhythmia recurrence within the year. Antiarrhythmic drugs may be effective predominantly in patients with electrical atrial remodelling (that is: AF induced action potential shortening, down regulation of ion channels or gap junctions). The role of the autonomic nervous system (ANS) in onset and perpetuation of AF remains incompletely understood. There are patients that specifically experience AF during high vagal tone, or, conversely during exercise. Therefore, the ANS plays a role in initiation of AF and in atrial autonomic remodelling in at least some, but probably in many patients. This notion, however, has had modest impact on the clinical care of patients.
Stimulation of the intrinsic cardiac ANS exerts both increased parasympathetic and sympathetic activity, leading to shortening of the atrial and pulmonary vein action potential duration (parasympathetic effect), and increase of intracellular [Ca2+] (sympathetic effect). The increased sympathetic activity observed in patients with AF may well be the result of the ongoing arrhythmia, rather than an independent phenomenon that causes the arrhythmia. In other words, it may be that patients with restoration of sinus rhythm will have a decrease in sympathetic tone, while other patients will remain a high tone. It is relevant to distinct between both causes, because it will heavily affect the targeted clinical strategy to prevent recurrence of AF in these patients.
However, subjecting every patient to invasive testing of the effect of the ANS to assess the patient specific effect is not feasible and exposes patients to potential adverse events. Hence, 123I-mIBG scintigraphy allows non-invasive quantification of the sympathetic activity in the heart.

Doel van het onderzoek

Patients with new-onset or recurrent AF have an altered myocardial sympathetic activity. The quantification of sympathetic activity with 123I-mIBG scintigraphy, as well as its change over time after restoration of sinus rhythm, can be used to target therapy and predict AF recurrence.

Onderzoeksopzet

Patients who are in AF and scheduled for an elective cardioversion will undergo 123I-mIBG scintigraphy within 7 days before and six week after the cardioversion. At the same moment, a blood sample (35 ml) will be collected. Patients will be followed for 1 year, with rhythm monitoring by a 24-hours Holter at 6 and 12 months. Furthermore, at these moments another blood sample (35 ml) will be collected. The blood samples will be analysed in collaboration with the "Bioinformatics Laboratory".

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

Amsterdam UMC - Locatie AMC
Joris R. de Groot

+31205666837

Wetenschappelijk

Amsterdam UMC - Locatie AMC
Joris R. de Groot

+31205666837

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Elective cardioversion is planned
- Adequate anticoagulation with vitamin K antagonists or NOACs for at least 3 weeks prior to the procedure
- Beta-blocker use at baseline, at least continued up to the second 123I-mIBG scintigraphy
- Age between 18 and 80 years
- Legally competent and willing and able to sign informed consent
- Willing and able to conform to the study protocol

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unable or unwilling to comply with study procedures
- Discontinuing of beta-blockers during follow-up period up to the second 123I-mIBG scintigraphy
- Discontinuing or switch of antiarrhythmic drugs during follow-up period up to the second 123I-mIBG scintigraphyArrhythmia other than AF as the indication for cardioversion
- Emergency electrical cardioversion
- Overt heart failure symptoms (i.e. oedema, pulmonary rales, orthopnoea), NYHA class≥2 and/or left ventricular ejection fraction < 35%
- Known significant coronary artery disease (>50% stenosis)
- Myocardial infarction or acute coronary syndrome within 3 months prior to the cardioversion
- History of catheter or surgical ablation for any arrhythmia
- A history of a thoracotomy
- CVA within 6 months prior to the cardioversion
- Active malignant disease
- History of neurosecretory tumours
- Pregnancy or of childbearing potential without adequate contraception
- History of previous radiation therapy of the thorax
- Circumstances that prevent follow-up (no permanent home or address, transient, etc.)
- Life expectancy <2 years.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
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Ethische beoordeling

Positief advies

Datum:	29-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8359
Ander register	METC AMC : 2019_244

Resultaten

Samenvatting resultaten
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