Atrial Fibrillation in Patients With an Implantable Cardioverter Defibrillator and Coronary Artery Disease.

Gepubliceerd: 19-12-2017 Laatst bijgewerkt: 15-05-2024

To investigate the incidence of new-onset AF in patients with coronary artery disease and an impaired LVEF, who will receive a single chamber ICD as primary prevention for sudden cardiac death.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28810

Bron
NTR

Verkorte titel
INDICO AF

Aandoening

Atrial fibrillation, implantable cardioverter defibrillator, home monitoring, coronary artery disease.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the percentage of patients with AF at 1 or 2 years.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Post-myocardial infarction patients with reduced left ventricular ejection fraction (LVEF) are indicated for Implantable Cardioverter-Defibrillator (ICD) therapy as primary prevention for sudden cardiac death (SCD). Timely detection of atrial fibrillation (AF) in ICD patients is clinically important for appropriate treatment for prevention of AF related complications, most importantly stroke, heart failure and inappropriate ICD shocks. Patients with a two- or three chamber ICD and coronary artery disease (CAD) show a higher incidence of AF than age matched controls. If CAD patients with a single chamber ICD carry a similar risk for AF remains unknown. Recently, single chamber ICDs including algorithm based rhythm recorders are developed to investigate the incidence and prevalence of AF.

Objective: To investigate the incidence of new-onset AF in patients with CAD and an impaired LVEF, who will receive a single chamber ICD as primary prevention for SCD.

Study design: This study will be a multicentre observational study. Patients with CAD and

Study population: Patients, with CAD, LVEF <35% and without a history of AF, who are indicated for a single chamber ICD as primary prevention for SCD.

Intervention: Patients will, as per guideline recommendation, receive a single chamber ICD with an algorithm based rhythm recorder.

Main study parameters: Main study parameters are new-onset or silent AF.

The study with regard to a broader research plan: This study will underscore the importance of AF detection in single chamber ICD patients, remote patient monitoring and improvement of patient care. Thereby it may serve as a pilot study for upcoming large international trials on AF detection algorithm in patients with single chamber ICDs.

Doel van het onderzoek

To investigate the incidence of new-onset AF in patients with coronary artery disease and an impaired LVEF, who will receive a single chamber ICD as primary prevention for sudden cardiac death.

Onderzoeksopzet

Standard ICD interrogation will take place on a quarterly basis. The occurrence of AF will be monitored via remote monitoring and documented in the eCRF every month, during one year or until we reach an event rate of 10% and 20%.

Onderzoeksproduct en/of interventie

Patients with CAD and

Contactpersonen

Publiek

Academic Medical Center-University of Amsterdam, F3-234

J.R. Groot, de
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5669111 (tracer 58921)

Wetenschappelijk

Academic Medical Center-University of Amsterdam, F3-234

J.R. Groot, de
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020-5669111 (tracer 58921)

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age between 65 and 80 years

• CAD, evident from a) previous myocardial infarction or b) revascularization through PCI or CABG

• LVEF<35%, quantified on MRI or with nuclear imaging

• Willing and able to sign informed consent and to comply with the protocol and with the follow-up

• Life expectancy > 2 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Unwilling or unable to comply with the protocol

• Unwilling to sign informed consent

• Current atrial fibrillation

• A history of atrial fibrillation

• Previous catheter or surgical ablation for atrial fibrillation

• Use of vitamin K antagonist or NOACs

• Use of class 1 or 3 antiarrhythmic drugs for ventricular or supraventricular arrhythmia ` other than AF

• Prosthetic heart valves

• Dilated or hypertrophic cardiomyopathy

• Congenital heart disease for which surgical correction was performed

• Inherited arrhythmia syndrome

• Active malignant disease

• Use of antracyclins in the history

• History of TIA, stroke or systemic embolism

• Being pregnant or of child bearing potential

• 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 nog niet gestart
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55649
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6732
NTR-old	NTR6910
CCMO	NL63311.018.17
OMON	NL-OMON55649

Resultaten