INDICO AF - Atrial Fibrillation in patients with an implantable cardioverter defibrillator and coronary artery disease.

Published: 04-05-2018
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To investigate the incidence of new-onset AF in patients with CAD and a single chamber ICD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON55649

Source
ToetsingOnline

Brief title
INDICO AF

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation, irregular heartbeat

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,AMC,Medtronic B.V.

Intervention

Keyword: Atrial Fibrillation (AF), Coronary Artery Disease (CAD), Implantable Cardioverter Defibrillator (ICD), Remote monitoring

Outcome measures

Primary outcome

- Incidence of new-onset AF in patients with CAD, LVEF <35 and no history of AF

with a single chamber ICD.

- The burden of AF in patients in whom we detect AF during this study.

Secondary outcome

- Time to an eventrate of 20% is reached.

- Determine if specific blood biomarkers reflecting different pathogenic

pathways in AF (fibrosis, oxidative stress and inflamtion), can be related tp

AF.

Study description

Background summary

Coronary artery disease (CAD) patients with reduced left ventricular ejection fraction (LVEF) are indicated for Implantable Cardioverter Defibrillator (ICD) therapy as 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 such as stroke and inappropriate ICD shocks. Patients with a two- or three chamber ICD and CAD show a higher incidence of AF. 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.

Study objective

To investigate the incidence of new-onset AF in patients with CAD and a single

chamber ICD.

Study design

This study will be a multicentre observational study. Patients with CAD, 35% and no history of AF will receive an single chamber ICD including an
algorithm based rhythm recorder. In combination with remote monitoring data will be collected every month during 1 year or until an event rate of 20%.
Blood drawing and a twelve lead ECG will be made on the day of implantation and during 6 and 12 months follow up, during standard ICD interoggation. All patients in whom AF is documented will be invited for an outpatient visit and will receive adequate anticoagulation treatment, when appropriate according to CHADSVASc score.

Study burden and risks

The risk of AF in a population of patients with CAD and a reduced LVEF is high, but the available data are derived from patients wit a two- or three chamber ICD. It is likely that patients with CAD and a reduced LVEF recieving a single chamber ICD for prevention of SCD carry a similar high risk for AF. Particpants will recieve a single chamber ICD including an alghorythm based rhythm recorder for the detection of AF. In order to detect AF, patients are asked to use the patient unit once a month to send the stored data to the AMC. Follow-up of patients will be performed in one of the participating centers at 6 and 12 months and every six months during standard ICD interrogation untill we reach an event rate of 20%. .Participants will have potential benefit through the early detection of AF and start of oral anticoagulation therapy.

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

• Age between 18 and 80 years
• CAD, evident from a) previous myocardial infarction or b) revascularization through PCI or CABG
• LVEF<35%, quantified on MRI, with nuclear imaging or determined by echocardiography
• Willing and able to sign informed consent and to comply with the protocol and with the follow-up
• Life expectancy > 2 years

Exclusion criteria

• Unwilling to sign informed consent
• Current atrial fibrillation
• A history of atrial fibrillation not including postoperative atrial fibrillation
• Previous catheter or surgical ablation for atrial fibrillation
• Current use or current indication 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
• Being pregnant or of child bearing potential

• Life expectancy<2 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2019
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Implantable Cardoverter Defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 28810
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63311.018.17
OMON	NL-OMON28810