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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28810

Source
NTR

Brief title
INDICO AF

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam
Source(s) of monetary or material Support: Medtronic

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1) the time to 10% and 20% of patients with AF.

2) The burden as percentage/day of AF.

3) Occurrence of TIA, stroke or systemic embolism.

4) Cumulative incidence of appropriate and inappropriate ICD therapy.

Study description

Background summary

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.

Study objective

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.

Study design

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%.

Intervention

Patients with CAD and

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55649
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results