Incidence of ventricular arrhythmias in patients with chronic total coronary occlusion recanalization

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON55852

Source
ToetsingOnline

Brief title
VACTOR -study

Condition

- Coronary artery disorders

Synonym
Chronic total occlusion of the coronary arteries; Ventricular arrhythmias

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chronic total coronary occlusion (CTO), Implatable loop recorder (ILR), Sudden cardiac death (SCD), Ventricular-arrhythmias (VA)

Outcome measures

Primary outcome

To assess the incidence of ventricular arrhythmias in patients with successful CTO recanalization, failed CTO recanalization, and untreated CTO during a follow-up period of 3 years. Ventricular arrhythmias will be defined as sustained ventricular tachycardia >30 s or ventricular fibrillation.

Secondary outcome

• To assess the occurrence of all-cause mortality

• To assess the occurrence of cardiovascular death

• To assess the occurrence of major adverse cardiac events (MACE). MACE include myocardial infarction, urgent revascularization, stroke, or death.

Study description

Background summary

Chronic total occlusion (CTO) is a common condition among patients with coronary artery disease, with a reported prevalence between 20% to 50% in patients with ischemia referred to the catheterization laboratory.1,2 Successful CTO recanalization has been associated with improved long-term survival in several non-randomized studies.3-10 A recent single-center study demonstrated that all-cause mortality was 17.2% for unsuccessful CTO recanalization and 4.5% for successful CTO recanalization at 5 years of follow-up.3 Interestingly, only a minority (7%) of the unsuccessful CTO recanalization population had a left ventricular ejection fraction (LVEF) <40%. There is limited data on the cause of death in this specific population.

Study objective

The objective of the present pilot study is to assess the incidence of sustained VA in 3 CTO groups: patients with successful percutaneous CTO recanalization (group A), patients with failed percutaneous CTO recanalization (group B), and patients with untreated CTO (group C).

Study design

Three-arm pilot study of patients with CTO.
A. patients who have undergone a successful percutaneous CTO recanalization;
B. patients who have undergone a failed percutaneous CTO recanalization;
C. patients with an untreated CTO

An ILR will be implanted to continuously monitor heart rate and rhythm during the follow-up period. There will be one extra outpatient clinic visit at 10 days after the procedure to inspect the wound. Every patient will have regular follow-up visits according to the local practice until battery depletion of the device (standard of care). The expected device longevity is approximately 3 years.

Study burden and risks

Patients will receive an ILR which is a small device that is placed subcutaneously using local anesthetics. The procedure will take approximately 10 minutes. There will be one extra outpatient clinic visit at 10 days after the procedure to inspect the wound. Every patient will have regular follow-up visits according to the local practice until battery depletion of the device (standard of care). The expected device longevity is approximately 3 years.

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

1. Presence of CTO defined as complete obstruction of the vessel with Thrombolysis In Myocardial Infarction (TIMI) flow grade 0 and an estimated duration of >=3 months, and one of the following:, a) A successful percutaneous CTO recanalization for stable angina within the previous 6 months. A successful CTO recanalization is defined as a final TIMI flow grade >=2 and a residual stenosis <=30% after stent. implantation., b) A failed percutaneous CTO recanalization for stable angina within the previous 6 months. A failed CTO recanalization is defined as not fulfilling the criteria for successful CTO recanalization., c) Untreated CTO diagnosed in the previous 6 months., 2. Age >=18 years;, 3. Written informed consent;, 4. Patient agrees to the follow-up including the implantation of the ILR.

Exclusion criteria

1. Patients who are potential candidates for an ICD according to the 2015 ESC guidelines., 2. Patients who have a cardiac implantable electrical device (e.g., pacemaker, ICD)., 3. Patient has reduced immune function or is otherwise at high risk for infection., 4. Patient has had a recent (within 30 days) or otherwise unresolved infection., 5. Known pregnancy at time of inclusion., 6. Patient has severe co-morbidity that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (i.e., less than one year).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2018
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Implantable Loop Recorder (ILR);Reveal Linq
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	21-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03475888
CCMO	NL59827.078.16