AmStErdam Cohort StUdy of Patients at Risk for VEntricular Arrhythmias

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The aim of this study is to investigate to what extent biomarkers are related to the development of ventricular arrhythmias, in order to improve the indication for ICD therapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON53817

Source
ToetsingOnline

Brief title
SECURE

Condition

- Cardiac arrhythmias

Synonym
sudden cardiac death, Ventricular arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Biomarkers, ICD, Sudden cardiac death, Ventricular arrhyhtmia

Outcome measures

Primary outcome

The expression of biomarkers in the serum of patients with and without appropriate therapy.

Secondary outcome

To determine novel biomarkers that may be associated with the onset of ventricular arrhythmias. This is done through proteomics. The patients with appropriate therapy are matched with patients without appropriate therapy. Subsequently, the protein profile is determined in both groups in order to see whether there are proteins that are elevated in the group with an arrhythmia and not in the group without an arrhythmia.

Study description

Background summary

Sudden cardiac death accounts for about 20% of all deaths in Europe. The implantable cardioverter defibrillator is designed to deliver a shock in the event of a fatal cardiac arrhythmia. An ICD is currently being implanted in several groups of patients who have an increased risk of developing a lethal ventricular arrhythmia. Currently, the most commonly used and known risk factor is having reduced left ventricular function measured as ejection fraction (LVEF). However, only a limited number of patients with an ICD actually develop an arrhythmia, while they are exposed to a risk of complications. In addition, there is still a group of people who die of sudden cardiac death without the protection of an ICD. In this study we look for potential biomarkers that are predictive of the occurrence of ventricular arrhythmias.

Study objective

The aim of this study is to investigate to what extent biomarkers are related to the development of ventricular arrhythmias, in order to improve the indication for ICD therapy.

Study design

Blood will be drawn during routine follow-up of patients with an ICD. This will happen at baseline, 6 and 12 months. If a patient receives appropriate therapy, blood will be taken 1 more time within two weeks after this therapy. These patients are matched on the basis of baseline characteristics to patients without appropriate therapy. In both groups, the levels of biomarkers are determined and it is examined whether they are elevated in the patients with therapy.

Study burden and risks

Patients will not directly benefit from this study. However, there is only a very small risk of complications associated with the collection of blood. This includes hematoma formation or scar tissue. The blood tests are linked as much as possible to visits for standard care.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with a primary prevention ICD, according to current EU guidelines
- Patients with no prior documented treated or untreated sustained ventricular arrhythmias
- >=18 years of age

Exclusion criteria

- Transvenous ICD implanted less than 3 months prior to inclusion
- Contra-indications for venepunctures
- CRT-D patients
- Patients with an ICD indication based on a channelopathy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2024
Enrollment:	245
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	02-10-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL83370.015.23