ExtraVascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study

Published: 27-01-2020
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See section 3.2 on protocol page 24The purpose of the clinical study is to demonstrate the safety and efficacy of the EV ICD System: a complete single-chamber extravascular ICD system with the lead implanted substernally

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

Summary

ID

NL-OMON54505

Source
ToetsingOnline

Brief title
EV ICD study

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disturbances, ventricular fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: EV ICD, EV ICD lead, EV ICD study, Pivotal

Outcome measures

Primary outcome

See section 4 on protocol page 24

Primary Safety Objective: Demonstrate the freedom from major complications related to the EV ICD System and/or procedure at 6 months post-implant exceeds 79% Objective Performance Criterion (OPC).

Primary Efficacy Objective: Demonstrate the EV ICD defibrillation testing success rate at implant is greater than 88% OPC.

Secondary outcome

See section 4 on protocol page 24

• Characterize appropriate and inappropriate shocks

• Characterize electrical performance (pacing capture thresholds, pacing impedance, sensing amplitudes) over time

• Characterize extracardiac pacing sensation

• Characterize asystole pacing

• Summarize ATP performance with spontaneous arrhythmias

• Summarize adverse events

• Characterize the EV ICD defibrillation testing success rate at 6 months

post-implant.

Study description

Background summary

See section 3.1 on protocol page 22

Today, implantable cardioverter defibrillator (ICD) therapy is the treatment of choice for patients who are at risk for sudden cardiac death due to life-threatening ventricular arrhythmias
However, these systems have limitations.
As a result, there is demand for novel ICD systems that circumvent the potential disadvantages of transvenous ICD systems by preserving the heart and vasculature.

Study objective

See section 3.2 on protocol page 24

The purpose of the clinical study is to demonstrate the safety and efficacy of the EV ICD System: a complete single-chamber extravascular ICD system with the lead implanted substernally

Study design

See section 5 on protocol page 26

The EV ICD Pivotal Study is a prospective, multi-center, single-arm, non-randomized, pre-market clinical study.
Enrollment will include up to 400 subjects at up to 60 sites worldwide.

Intervention

Implantation of EV ICD system

Study burden and risks

See section 9 on protocol page 77

The unique risks introduced by the EV ICD System include: unique harms associated with procedural complications, unique harms associated with defibrillating from a substernal lead position, unique harms from chronic lead

implant in the substernal space, and the general risk that an EV ICD System has not yet been chronically implanted in humans for greater than 12 months.

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

Patient has a Class I or IIa indication for implantation of an ICD according to the Guidelines.
Patient is at least 18 years of age.

Exclusion criteria

Patient is unwilling or unable to personally provide Informed Consent.
Patient has indications for bradycardia pacing x or Cardiac Resynchronization Therapy (CRT).
Patients with an existing pacemaker, ICD, or CRT device or leads.
Patients with medical interventions or specific medical conditions as specified in CIP.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	EV ICD
Registration:	No

Ethics review

Approved WMO Date:	27-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-08-2021

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT04060680
CCMO	NL71101.100.19