Post market clinical follow-up study for the Pamira ICD lead family.

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Collect clinical data in order to confirm the clinical safety and performance of the Pamira lead when used in routine clinical practice to support the regulatory post-market strategy in Europe and other regions and validation of promotional claims...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON56034

Source
ToetsingOnline

Brief title
BIO|MASTER.Pamira study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: BIOTRONIK SE & Co.KG
Source(s) of monetary or material Support: BIOTRONIK SE & Co. KG

Intervention

Keyword: cardiac arrhythmias, Implantable Cardioverter Defibrillator (ICD)

Outcome measures

Primary outcome

The primary objective is to collect clinical data on the performance and safety of the Pamira lead by analyzing the Pamira related SADE-d events occurring during the implantation or in the 6 months thereafter.

Secondary outcome

Secondary objective is to confirm the clinical safety by analyzing the Pamira-related SADE-d events occurring during the implantation or in the 3 and 12 months thereafter, as well as the assessment of the appropriateness of right ventricular sensing and pacing at the 6- and 12-month FU.

Study description

Background summary

The Pamira lead, has been CE approved in the European Union since January 2023. This means that the Pamira lead fulfils the European regulatory requirements for medical device products and therefore can be used in patients with an ICD indication (also outside clinical investigations). However, the regulatory approval process also requires the collection of clinical data on the performance and safety of the lead after market approval (PMCF as requested by the MDR) when used within routine clinical practice. Thus, this study intends to collect data which will be used for regulatory purposes (MDR).

Study objective

Collect clinical data in order to confirm the clinical safety and performance of the Pamira lead when used in routine clinical practice to support the regulatory post-market strategy in Europe and other regions and validation of promotional claims by:
• demonstrating clinical safety

• evaluating performance based on sensing and pacing assessment
• collecting additional data of interest to assess other aspects such as the handling and usability

Study design

Prospective, multi-center, international, open, single-arm study.

Intervention

Collection of safety and performance data during the implantation and FUPs of a BIOTRONIK ICD with usage of a Pamira lead. A strict FUP schedule needs to be followed in order to collect the necessary endpoint data from a device interrogation at the 3-, 6- and 12-month FUP after the implantation + usage of the BIOTRONIK Home Monitoring system.

Study burden and risks

This study is classified as a PMCF without invasive and/or burdensome procedures. As the implantation of the Pamira ICD lead does not differ from the standard implantation procedure of ICD leads, no study specific risks are associated with the implantation procedure. There are however possible risks that we do not know about at the moment (residual risks), even in a post market setting (after successful conformity assessment).

The timing of the study follow-up visits (3-, 6- & 12-month follow up) might differ from the standard routine in the participating hospitals. The duration of the follow-up visits is slightly increased compared to the routine follow-ups due to the data collection for the study on the device features. The usage of Home Monitoring is mandatory but this is not a burden rather an advantage for the early detection of events as this is in line with the current Guidelines (already since 2015 the usage of Home Monitoring is endorsed by the HRS guidelines: with a Class I (A) recommendation that all patients with an Cardiac Implantable Electronic Device should be offered Remote Monitoring as part of the standard FUP management)

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

Standard indication for ICD therapy according to clinical guidelines.
Planned for de novo implantation of a BIOTRONIK ICD in combination with a Pamira ICD lead.
Ability and willingness to use the "CardioMessenger" and acceptance of the BIOTRONIK Home Monitoring® concept.
See CIP 8.3.1.

Exclusion criteria

Mechanical tricuspid valve prosthesis or a severe tricuspid valve disease.
Cardiac surgical post-implantation procedure planned within 12 months.
See CIP 8.3.2.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Pamira ICD lead family
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-10-2023
Application type:	First submission
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	NCT05621187
CCMO	NL84823.078.23