Pivotal study of the Amvia pacemaker and Solia CSP S pacing lead on conduction system pacing.

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This study is designed to support the regulatory requirements for obtaining the CE mark for the Solia CSP S lead and to support post-market clinical follow-up requirements for the Amvia family (PMCF). Therefore the primary objective is to show…

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

Summary

ID

NL-OMON57316

Source
ToetsingOnline

Brief title
BIO|MASTER.CSP

Condition

- Cardiac arrhythmias

Synonym
Bradyarrhythmia, slow heart rate with irregular heart rhythm

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: Bradyarrhythmia, Conduction System Pacing (CSP), Heart failure

Outcome measures

Primary outcome

Primary endpoint 1 - Amvia related SADE-d free rate through 6 months (in a PMCF setting)

The safety of Amvia pacemakers will be investigated in a PMCF setting by determining the SADE-d free rate at 6 months (183 days) after implantation.

SADEs will be considered as primary endpoints if they are possible, probable or causal related to an investigational device. Purely procedure-related SADEs (SADE-p) will not be considered.

An internal board will adjudicate SADEs whereby the seriousness and device relatedness will be re-examined. If any amply documented external physical influence (e.g. accident, sport, twiddling, pneumothorax) or medical AE caused the SADE, it does not contribute to this endpoint.

Primary endpoint 2 - Solia CSP S related SADE-d free rate through 6 months (in a pre-CE label setting)

The safety of the Solia CSP S pacing lead will be investigated (to support the regulatory requirements to obtain CE mark) by determining the SADE-d free rate at 6 months (183 days) after implantation. SADEs will be considered as primary endpoints if they are possible, probable or causal related to an investigational device. Purely procedure related SADEs (SADE-p) will not be considered.

An internal board will adjudicate SADEs whereby the seriousness and device relatedness will be re-examined. If any amply documented external physical influence (e.g. accident, sport, twiddling, pneumothorax) or medical AE caused the SADE, it does not contribute to this endpoint.

Secondary outcome

Secondary endpoint 1 - Amvia related SADE-d free rate through 12 months (in a PMCF setting)

The safety of Amvia pacemakers will be investigated by determining the SADE-d free rate at 12 months (365 days) after implantation. The same definitions and adjudication procedures as for the primary endpoints apply.

Secondary endpoint 2 - Solia CSP S related SADE-d free rate through 12 months (in a Pre-CE label setting)

The safety of the Solia CSP S pacing lead will be investigated by determining the SADE-d free rate at 12 months (365 days) after implantation. The same definitions and adjudication procedures as for the primary endpoints apply.

Secondary endpoint 3 - Rate of successful acute CSP implantation of Solia CSP S

All implantations, in which the investigator decides to leave the Solia CSP S pacing lead permanently in the conduction system, are counted as acute success.

Secondary endpoints 4a and 4b - Appropriateness of sensing (a) and pacing (b) performance

For the pacing system performance, investigators will be asked whether the

pacing and sensing is adequate at implantation and during follow-up.

Secondary endpoint 5 - Maintenance of physiologic ventricular excitation based on ECG

At implantation and at the end of each follow-up the investigator is asked to assess the LBBAP capture response based on the interpretation of a 12-lead ECG recording according to the ECG-hallmarks of successful stimulation in the LBBA.

Secondary endpoint 6 - Mid-term change in LVEF and LVESV

To monitor possible cardiac remodeling in all patients LVEF and LVESV values shall be collected at baseline, at the 6-month follow-up, at the 12-month follow-up and at all following annual in-office follow-ups, if applicable.

Secondary endpoint 7 - Mid-term change in quality of life

To monitor mid-term changes in quality of life, Health-related quality of life (HRQoL) questionnaires will be filled out by each patient at baseline, at the 6-month follow-up, at the 12- month follow-up and at all following annual in-office follow-ups, if applicable.

Study description

Background summary

Permanent cardiac pacemaker devices, including cardiac resynchronization therapy pacemaker devices, are essential for treating symptomatic bradycardia and heart block. Recently, physiological pacing approaches such as left bundle branch area pacing (LBBAP) have emerged as alternative strategies. These

methods directly pace the conduction system, enabling a more physiological excitation of the heart. Increasing clinical evidence suggests that conduction system pacing (CSP) can prevent pacing-induced cardiomyopathy and mitigate the development or worsening of heart failure.

The 'Amvia' pacemaker family represents BIOTRONIK*s latest generation of pacemakers that is available on the market for usage with CSP. The pacemakers and pacing leads investigated in this study are designed to meet the specific requirements of CSP. The Amvia Sky/Edge pacemakers are already available on the European market and contain a software tag to indicate the implantation of the right ventricular lead in the LBB area. The Solia CSP S pacing lead is a bipolar, 6F, active fixation, steroid-eluting pacing lead with an IS-1 connector that is specifically developed for usage with CSP.

Our research project is submitted as a clinical investigation involving two investigational devices used in combination for Conduction System Pacing (CSP). Due to its design and the use of the Solia CSP S lead in a pre-CE label setting, this clinical investigation falls under Article 62 of the Medical Device Regulation. This supports the regulatory requirements for obtaining the CE mark for the Solia CSP S lead. Additionally, BIOTRONIK will use the results to fulfill Post-Market Clinical Follow-up requirements for the Amvia pacemaker family.

Study objective

This study is designed to support the regulatory requirements for obtaining the CE mark for the Solia CSP S lead and to support post-market clinical follow-up requirements for the Amvia family (PMCF). Therefore the primary objective is to show clinical safety of the Amvia pacemakers (in a PMCF setting) and the Solia CSP S leads (in a pre-CE label setting) when used for CSP by analyzing the related SADE-d events occurring during the implantation or in the 6 months thereafter.
Secondary objective is to confirm the clinical safety of Amvia pacemakers (in a PMCF setting) and Solia CSP S leads (in a pre-CE label setting) when used for CSP by analyzing the related SADE-d events through 12 months after implantation, as well as the appropriateness of sensing and pacing of the system during follow-up.

Study design

Open, prospective, international, multi-center, nonrandomized study

Intervention

Pacemaker or CRT-P pacemaker (with CE-mark) with usage of CSP and the Solia CSP

S lead (pre-CE label).

Study burden and risks

Two health-related quality of life questionnaires (SF36 and EQ-5D-5L) will be taken; at enrollment, 6 month,12 month and during the annual follow up visit.

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

For patient enrollment in the study all of the following inclusion criteria have to be fulfilled at the time of enrollment:
• Standard indication for de novo pacemaker implantation or cardiac

resynchronization therapy
• Patient is intended for implantation of a pacemaker or CRT-P system with left bundle branch area stimulation
• Ability to understand the nature of the study
• Ability and willingness to perform all follow-up visits at the study site
• Ability and willingness to use the CardioMessenger and acceptance of the BIOTRONIK Home Monitoring concept

Exclusion criteria

Enrollment of a patient is not permitted if at least one of the following criteria is fulfilled:
• Planned cardiac surgical procedures or interventional measures other than the study procedure within the next 12 months
• Expected to receive heart transplantation or ventricular assist device within 12 months
• Life-expectancy less than 12 months
• Pregnant or breast feeding
• Age less than 18 years
• Participation in another interventional clinical investigation (refer to section 8.3.2 study protocol for details)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Generic name:	Solia CSP S pacing lead (pre-CE-mark) + Amvia pacemaker (with CE-mark in a PMCF setting)
Registration:	No

Ethics review

Approved WMO Date:	19-02-2025
Application type:	First submission
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	NCT06620237
CCMO	NL83481.000.23