The LEADLESS II Study;
A safety and effectiveness trial for a leadless pacemaker system

Published: 15-02-2021
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The primary objectives of this study are to confirm the clinic al safety and effectiveness of the Aveir LP system in subjects who are indicated for VVI(R) pacemaker.

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

Summary

ID

NL-OMON54305

Source
ToetsingOnline

Brief title
Leadless II

Condition

- Cardiac arrhythmias

Synonym
cardiac arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: bradycardia, cardiac arrhythmias, leadless pacemaker, percutaneous procedure

Outcome measures

Primary outcome

The confirmatory safety endpoint evaluates the 12-month complication-free rate.

The confirmatory effectiveness endpoint evaluates pacing thresholds and R-wave amplitudes within the therapeutic range through 12-months post-implant.

Secondary outcome

The confirmatory secondary endpoint evaluates an appropriate and proportional rate response during graded exercise testing (CAEP protocol), performed between the 6-week and 3-month visit.

Study description

Background summary

The clinical investigation for the IDE application to support the evaluation of the safety and effectiveness of the St. Jude Medical LP system for treatment of bradycardia consists of two phases:

Phase 1 included the evaluation of St. Jude Medical*s original NanostimTM Leadless Pacemaker system consisting of LP Model S1DLCP and its supporting accessories (ClinicalTrials.gov identifier: NCT02030418). As of this protocol, Phase 1 has completed the primary safety and effectiveness endpoint analyses, submitted the PMA application, and is currently under the Continued Access Phase (CAP). Due to device malfunctions related to the battery and docking button, the Nanostim system was discontinued.

Phase 2 is described within this clinical investigational plan and includes the confirmatory evaluation of the modified St. Jude Medical LP system consisting of a modified LP, model LSP112V and its supporting accessories, herein referred to as the AveirTM Leadless Pacemaker System. Study subjects who are newly

implanted (de novo) with the Aveir LP will contribute to the confirmatory endpoints and follow Phase 2 protocol requirements. European subjects enrolled in the Leadless Observational Study (NCT#02051972) involving the original Nanostim LP who need replacement of their Nanostim LP with the Aveir LP may be enrolled in this IDE only after the confirmatory enrollments have been completed for Phase 2 (i.e. during the CAP for Phase 2).

Study objective

The primary objectives of this study are to confirm the clinic al safety and effectiveness of the Aveir LP system in subjects who are indicated for VVI(R) pacemaker.

Study design

The Leadless II Study - Phase 2 is a prospective, non-randomized, multi-center, international clinical study

Intervention

Implantation of an Aveir leadless pacemaker - model LSP112V

Study burden and risks

The patients will visit the hospital at 3 additional timepoints in the first year for a study visit, compared to patients who receive a wireless pacemaker according to standard care. The visits 6 months after an annual check-up are also extra compared to the standard care.

The risks of implantation are comparable to those of implantation of wireless pacemakers that are commercially available.

This study includes exposure to radiation for X-rays and pictures of the chest. The radiation dose in this study is comparable to that of currently approved pacemaker implantation and follow-up procedures.

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 Subject must have one of the clinical indications before device implant in adherence
with Medicare, ACC/AHA/HRS/ESC single chamber pacing guidelines including:
* Chronic and/or permanent atrial fibrillation with 2 or 3° AV or bifascicular bundle branch block
(BBB block), including slow ventricular rates (with or without medication) associated with atrial
fibrillation; or
* Normal sinus rhythm with 2 or 3° AV or BBB block and a low level of physical activity or short
expected lifespan (but at least one year); or
* Sinus bradycardia with infrequent pauses or unexplained syncope with EP findings; and
2. Subject is >=18 years of age; and
3. Subject has a life expectancy of at least one year; and
4. * Subject is not be enrolled in another clinical investigation; and
5. Subject is willing to comply with clinical investigation procedures and agrees to return for all
required follow-up visits, tests, and exams; and
6. Subject has been informed of the nature of the study, agrees to its provisions and has provided a

signed written informed consent, approved by the IRB; and
7. Subject is not pregnant and does not plan to get pregnant during the course of the study.

* Except for subjects who are enrolled in the Leadless Observational Study and need their existing Nanostim LP replaced with the Aveir LP. These subjects may only be enrolled in this IDE during the CAP study of Phase 2.

Exclusion criteria

1. Subject has known pacemaker syndrome, has retrograde VA conduction, or suffers a
drop in arterial blood pressure with the onset of ventricular pacing; or
2. Subject is allergic or hypersensitive to < 1 mg of dexamethasone sodium phosphate
(DSP);
3. Subject has a mechanical tricuspid valve prosthesis; or
4. Subject has a pre-existing endocardial pacing or defibrillation leads; or
5. Subject has current implantation of either conventional or subcutaneous implantable cardioverter
defibrillator (ICD) or cardiac resynchronization therapy (CRT) device; or
6. Subject has an implanted vena cava filter; or
7. Subject has evidence of thrombosis in one of the veins used for access during the procedure; or
8. Subject had recent cardiovascular or peripheral vascular surgery within 30 days of
enrollment; or
9. * Subject has an implanted leadless cardiac pacemaker
10.* Subject is implanted with an electrically-active implantable medical device with stimulation
capabilities (such as neurological or cardiac stimulators).

* Except for subjects who are enrolled in the Leadless Observational Study and need their existing Nanostim LP replaced with the Aveir LP. These subjects may only be enrolled in this IDE during the CAP study of Phase 2.
* Does not apply to a medical device known to not be impacted by the AveirTM Link Module telemetry signals or to a medical device than can be temporarily turned off during interrogation/programming of an AveirTM LP.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2021
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Aveir TM Leadless Pacemaker; LSP112V
Registration:	No

Ethics review

Approved WMO Date:	15-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam)

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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	NCT02030418
CCMO	NL75132.018.20