AveirTM DR i2i Study: Aveir Dual-Chamber Leadless i2i IDE Study

Published: 10-03-2022
Last updated: 05-04-2024

The purpose of this study is to evaluate the safety and effectiveness of the Aveir wireless dual-chamber pacemaker system in the treatment of patients with slow or irregular heartbeats.

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

Summary

ID

NL-OMON50262

Source
ToetsingOnline

Brief title
AVEIR DR

Condition

- Cardiac arrhythmias

Synonym
bradycardia, slow-heartrate

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bradyarrhythmia, DDD-Pacemaker, dual-chamber, leadless

Outcome measures

Primary outcome

The primary safety endpoint evaluates the 12-month Aveir DR LP system complication-free-rate in de novo subjects based on CEC adjudication of adverse events.

The primary effectiveness endpoint #1 evaluates the 12-month composite success rate of acceptable atrial pacing thresholds and P-wave amplitudes in de novo subjects.

The primary effectiveness endpoint #2 evaluates the 3-month AV synchrony success rate at rest while seated in de novo subjects.

Secondary outcome

The secondary safety endpoint evaluates the 12-month Aveir atrial LP complication free rate in de novo subjects based on CEC adjudication of adverse events.

The secondary effectiveness endpoint evaluates the appropriate and proportional rate response of the atrial LP in de novo subjects during graded exercise testing (chronotropic assessment exercise protocol *CAEP*).

Study description

Background summary

Cardiac pacing has been an established therapy for patients with bradyarrhythmia for over 50 years. However, this life-improving therapy is still associated with significant complications, primarily related to the transvenous lead and the subcutaneous pulse generator pocket.

Short-term complication rates as high as 8% to 12% have been reported, and include pneumothorax, cardiac tamponade, pocket hematoma, and lead dislodgement. In the long term, these leads are also prone to insulation breaks and conductor fracture, requiring re-intervention that puts the patient at risk for significant morbidity. Furthermore, 0.7% to 2.4% of patients encounter serious complications related to the subcutaneously placed pulse generator that include skin erosion, pocket infection, and septicemia.

The complications associated with the conventional transvenous pacemaker design have triggered the clinical need to eliminate the pacemaker lead, pockets and connectors through a fully self-contained leadless pacemaker system that can be implanted percutaneously with a steerable catheter, thus offering patients a less-invasive approach as compared to conventional pacemaker procedures that require more extensive surgery. The leadless concept was also designed to improve patient comfort by eliminating the visible lump and scar at a conventional pacemaker*s pectoral implant site and by removing the need for activity restrictions to prevent dislodgement or damage of a conventional lead.

As of the end of 2020, only two single-chamber leadless pacemaker models are commercially available while others are in development or under clinical investigation. Despite the cardiac rhythm management advances demonstrated from conventional transvenous pacemaker to single chamber leadless pacemaker systems, most patients require dual chamber pacing because of their clinical presentation.

Patients who are indicated for dual-chamber pacing would benefit from a dual-chamber leadless pacemaker system that provides atrial and ventricular bradycardia therapy while eliminating the long-term complications associated with the surgical pocket and transvenous atrial and ventricular leads that are associated with conventional pacing systems.

Currently, there are no leadless pacing systems capable of DDD(R) pacing. The Aveir DR LP system is a promising new technology that can deliver DDD(R) pacing therapy while also offering advantages over transvenous dual-chamber pacemakers for the treatment of bradyarrhythmias. The Aveir DR LP system is expected to provide comparable bradycardia treatment as transvenous dual-chamber pacemakers

for patients indicated for similar conditions.

Study objective

The purpose of this study is to evaluate the safety and effectiveness of the Aveir wireless dual-chamber pacemaker system in the treatment of patients with slow or irregular heartbeats.

Study design

This is a prospective, multi-center, international, single-arm, pivotal investigational study designed to evaluate the safety and effectiveness of the Aveir DR LP system in a subject population indicated for a DDD(R) pacemaker.

Intervention

2 Leadless pacemakers are implanted in all subjects. If a subject already has a leadless Aveir implanted, a second Aveir is placed in the right atrium.

Study burden and risks

Possible risks and discomforts associated with participation in the study will be similar to those associated with any routine dual-chamber pacemaker implantation procedure and related follow-up procedures. For the study there is an additional visit to the hospital after the implant-procedure, compared to the standard of care after implant of a traditional pacemaker.

Study-specific assessments that are not considered standard of care include femoral vein access instead of subclavian vein access, six-minute walk test and treadmill tests for rate response evaluation, in-clinic AV Synchrony assessments, 24-hour Holter monitoring, and EQ-5D quality of life assessment. A subject may experience fatigue, shortness of breath, chest pain and/or leg cramps during six minute walk and treadmill tests; this is mitigated by performing this test under the supervision of a trained professional and in a testing area where medical care is immediately available.

It is concluded from preclinical data (risk analysis and literature review) that clinical risks are comparable to those associated with currently available therapy (transvenous dual-chamber pacing). Uncertainty exists in relation to risks associated with novel features (percutaneous delivery via a femoral vein and the possibility dislodgement or migration). These residual risks cannot be estimated with confidence without data from a clinical investigation. Taking into account the nature of the possible harm that could arise from these device-related risks and the assurance provided by pre-clinical data, the risk-benefit balance associated with the use of the LP in a clinical trial is

considered to be favorable.

Contacts

Public
Abbott Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL
Scientific
Abbott Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject must have at least one of the clinical indications before device implant in adherence
with ACC/AHA/HRS/ESC dual chamber pacing guidelines
2. Subject is >= 18 years of age or age of legal consent, whichever age is greater
3. Subject has a life expectancy of at least one year
4. Subject is willing to comply with clinical investigation procedures and agrees to return to clinic
for all required follow-up visits, tests, and exams

5. Subject has been informed of the nature of the clinical investigation, agrees to its provisions
and has provided a signed written informed consent, approved by the IRB/EC

Exclusion criteria

1. Subject is currently participating in another clinical investigation that may confound the results
of this study as determined by the Sponsor
2. Subject is pregnant or nursing and those who plan pregnancy during the clinical investigation
follow-up period
3. Subject has presence of anatomic or comorbid conditions, or other medical, social, or
psychological conditions that, in the investigator*s opinion, could confound the assessment of
the investigational device and/or implant procedure, limit the subject*s ability to participate in
the clinical investigation or to comply with follow-up requirements of the clinical investigation
results
4. Subject has a known allergy or hypersensitivity to < 1 mg of dexamethasone sodium
phosphate or any blood or tissue contacting material listed in the IFU
5. Subject has an implanted vena cava filter or mechanical tricuspid valve prosthesis
6. Subject has pre-existing, permanent endocardial pacing or defibrillation leads (does not include
lead fragments)
7. Subject has current implantation of either conventional or subcutaneous implantable
cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT) device
8. Subject has an implanted leadless cardiac pacemaker (except for an Aveir ventricular LP)
9. Subject is implanted with an electrically-active implantable medical device with stimulation
capabilities (such as neurological or cardiac stimulators)*
10. Subject is unable to read or write

*NOTE: Does not apply to a medical device with no known impact to the Aveir Leadless Pacemaker System, including the Aveir Link Module. Patient evaluation and the decision to implant the LP should take into account the presence of other active implantable devices and should include consultation with the

Sponsor and/or manufacturer of the co-existing device.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2022
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Aveir DR LP System
Registration:	No

Ethics review

Approved WMO Date:	10-03-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2023

Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	28-06-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL79310.000.21