NANOSTIM SAFETY AND PERFORMANCE TRIAL FOR A LEADLESS CARDIAC PACEMAKER SYSTEM

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To evaluate the safety and clinical performance of the LCP system in patients 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-OMON36843

Source
ToetsingOnline

Brief title
The LEADLESS Study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrhythmia, irregular heartbeat

Research involving
Human

Sponsors and support

Primary sponsor: Nanostim, Inc.
Source(s) of monetary or material Support: Nanostiom;Inc.

Intervention

Keyword: irregular heart beat, leadless pacemaker, safety and performance

Outcome measures

Primary outcome

The primary safety endpoint is to evaluate a 90-day complication rate, where a

complication is defined as a serious adverse device effect (SADE)

Secondary outcome

To report pacing, sensing, and rate-response performance, implant success rate,

and safety analysis with reporting of all adverse events.

Study description

Background summary

The normal heart rhythm can be disturbed due to disease or aging.
This can result in problems with the conduction system of the heart. The impulse from the sinus node can be delayed or even blocked passed. This causes a slow and / or irregular heartbeat. A solution is a pacemaker. The pacemaker functions as a guardian of the heart rhythm by continuously monitoring the heart rate and, if necessary, regulate the heart rhythm.
Most of the complications of a standard pacemaker, are due to the electrode wires (leads). Nanostim has developed a leadless pacemaker which should encounter these specific complications.

Study objective

To evaluate the safety and clinical performance of the LCP system in patients who are indicated for VVI(R) pacemaker.

Study design

Prospective, non-randomized, single-arm, multicenter study.

Intervention

Percutaneous insertion of the leadless LCP system.

Study burden and risks

There is no guarantee that the subject will benefit of participating in the research . It is possible that the risk of an irregular or slow heartbeat, which can cause dizziness, fainting, extreme fatigue and shortness of breath, decreases.
It is thanks to this type of research that better treatments for irregular or slow heartbeat can be developed.

Every medical procedure carries risks with it. Since the Nanostim pacemaker is an investigational device, some risks are not known. As with any surgery, there may be complications during or after pacemaker implantation. Fortunately this is not common and they can usually be treated or corrected. Possible complications include:
* infection
The biggest risk is a replacement of the pacemaker;
* clot formation in the blood
* damage of the heart wall
* technical problems with the pacemaker
* blood loss as a result of the (after) bleeding from the surgical wound
* a reaction to the medications used during surgery;
* The pacemaker syndrome: The patient gets a pounding feeling in head, chest or abdomen and sometimes dizzy and constantly tired .

In this clinical trial, there is a small amount of exposure to radiation during angiography (X-ray of the arteries). In daily life, everyone is exposed to natural background radiation and it is exposed to a dose of about 2 millisieverts (mSv: is a measure of radiation) per year. The effective dose resulting from this treatment is estimated at a maximum of 0.4 mSv.

Pregnant women are excluded from this study. This applies to the entire study. It is not known what the consequences of participating in the study are to your unborn child.

The study doctor will discuss the procedure and the potential complications extensively discuss with the patient.

Contacts

Public
Nanostim, Inc.

Palomar Avenue 776
Sunnyvale 94085
US
Scientific
Nanostim, Inc.

Palomar Avenue 776
Sunnyvale 94085
US

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 following clinical indications:
* Chronic atrial fibrillation1 with 2 or 3° AV or bifascicular bundle branch block (BBB block)2; 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 *18 years of age; and
3. Subject has life expectancy of at least one year; and
4. Subject is not 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 written informed consent, approved by the EC; and
7. If female, for 3 months post-operative, subject will actively practice a contraception method, or will practice abstinence, or is surgically sterilized, or is postmenopausal.

Exclusion criteria

1. Pacemaker dependent; or
2. Known pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing; or
3. Hypersensitivity to < 1 mg of dexamethasone sodium phosphate; or
4. Mechanical tricuspid valve prosthesis; or
5. Pre-existing pulmonary arterial (PA) hypertension3 or significant physiologically-impairing lung disease; or
6. Pre-existing pacing or defibrillation leads; or
7. Current implantation of an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT); or
8. Presence of implanted vena cava filter; or
9. Presence of implanted leadless cardiac pacemaker; or
10. Pregnant or breastfeeding.

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):	21-12-2012
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Nanostim□s LCP system
Registration:	No

Ethics review

Approved WMO Date:	07-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT01700244
CCMO	NL42207.018.12