Clinical Evaluation of Safety and Performance of the BackBeat Moderato System

Published: 30-08-2013
Last updated: 25-04-2024

To evaluate the safety and performance of the BackBeat Moderato system.

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

Summary

ID

NL-OMON40595

Source
ToetsingOnline

Brief title
Moderato study

Condition

- Cardiac arrhythmias
- Vascular hypertensive disorders

Synonym
Hypertension

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dual chamber pacemaker, hypertension, safety and performance

Outcome measures

Primary outcome

A. Pacemaker phase

A.1. Primary performance endpoint

Moderato pacing performance will be evaluated through analysis of 24 hour Holter monitoring recordings. Additionally, the pacemaker performance will be evaluated by temporarily programming the IPG to different modes (including DDD, VVI) with different rate and timing parameters to evaluate appropriate clinical pacemaker performance.

A.2. Primary safety endpoint

Incidence of device- and treatment-related serious adverse events through the peri-procedural and 3-month follow-up period.

B. Hypertension phase

B.1. Primary performance endpoint

Moderato - HTN device performance will be evaluated through analysis of 24 hour Holter monitoring recordings.

B.2. Primary safety endpoint

Incidence of device- and treatment-related serious adverse events through 3

months of treatment.

Secondary outcome

In addition to the above noted endpoints, the additional endpoints listed below will be measured. For each of these parameters, the baseline values determined at the visit just prior to initiation of the Moderato-HTN therapy will be compared to the final values determined at the 3 month visit. The one exception to this is that the baseline echocardiogram will be the one obtained during the original study screening period.

• Change in average diastolic blood pressure after 3 months of treatment

• Change in the daytime-nighttime difference in BP after 3 months of treatment

• Change in the average nighttime BP after 3 months of treatment

• Change in left ventricular ejection fraction (by echocardiography) after 3 months of treatment

• Changes in proteinuria after 3 months of treatment

• Incidence of the occurrence of *pacemaker syndrome*

• Changes in serum neurohormone levels (BNP)

• Incidence of device malfunction

Study description

Background summary

Hypertension (HTN) ultimately affects 1 in 3 adults in most cultures and is one of the most important factors contributing to cardiovascular morbidity and mortality. Medications are usually effective in controlling blood pressure, >40% of HTN patients remain with unacceptably high blood pressure. Dual-chamber pacing is recommended for the management of symptomatic bradycardia due to sick sinus syndrome, atrio-ventricular block, a combination

of these conditions or other situations in which patients are prone to brady-arrhythmias. Currently available devices have evolved from simple single-chamber, fixed-rate pacemakers to multi-chamber, rate-responsive units. Pacemaker technology is well established, with well-defined hardware, firmware and logic algorithms. The Backbeat Moderato system incorporates such traditional pacing modes and algorithms to provide pacing support to patients with all conditions currently indicated for dual chamber pacing.

Study objective

To evaluate the safety and performance of the BackBeat Moderato system.

Study design

Prospective, non-randomised, multi-centric study.

Intervention

Standard implantation of a dual chamber pacemaker and the activation of the MOderato-HTN therapy.

Study burden and risks

Patients enrolled in this study have a clinical indication for implant of a permanent pacemaker and will therefore undergo the procedure required for implantation of the Moderato system whether or not they participate in this study. The potential added risks therefore relate to those associated with the delivery of the Moderato-HTN signals. The two aspects of risks can be summarized as follows:
Risks associated with Moderato implant (these are the risks to which the patient would be exposed independent of participation in the study):

As with the placement of a standard pacemaker, there are risks of complications that may occur during or after the procedure. With standard pacemakers these complications are uncommon and they can usually be cured or treated. Possible complications include infection, blood clots in the blood, damage of the heart wall, technical problems with the pacemaker, lead dislodgement or lead fracture, a reaction to drugs used during surgery, damage to the arteries or veins in the implant site, and pacemaker syndrome (ie the patient has an oozing sensation in the head, chest or abdomen and sometimes dizzy and tired continued).

The potential added risks associate with Moderato-HTN therapy may include:
a. Development of heart failure
b. Palpitations
c. Low blood pressure

d. Stroke
e. Kidney Dysfunction
f. Development of unusual patient sensations, pain or discomfort
g. Device malfunction which may require device replacement or explantation
h. Heart attack
i. Arrhythmias, including atrial fibrillation, atrial tachycardia
j. Increase in heart rate due to activation of the neurohormonal system

Since the Moderato-HTN therapy is experimental, there may be risks that are not yet known.

Pregnant women or women who may become pregnant during the study may only participate if they are willing to use contraception during the course of the study The doctor will discuss this further with the subject. If the subject becomes pregnant during the study, she should immediately inform the study doctor.

Benefits
The blood pressure may decrease as a result of the Moderato-HTN therapy. The study will determine the degree to which this benefit can occur.
In addition, the subject will receive the Pacemaker trearment that he/ she needs.
It is thanks to this type of research that better treatments for persistent hypertension can be developed.

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 is >= 18 years of age
2) Subject is indicated for implantation or replacement of a dual chamber permanent pacemaker where no lead extraction is necessary.
3) Subject has stable (for prior 2 months) regimen of 2 or more maximally tolerated anti-hypertension medications (of different drug classes), which is anticipated to be able to be maintained without changes for 3 months.
4) Subject has office systolic blood pressure measurement > 140 mmHg on two separate days within a one week period prior to enrollment, and the average of these two measurements is >=150 mmHg. All measures are to be taken prior to morning medication (e.g. 7-10AM). If the average of the two systolic blood pressure measurements is not >=150 mmHg, or one of the BP readings is less than 140 mmHg, a third measurement can be taken, with the same stability criterion applied for study eligibility.
5) Proximity to study center which will permit compliance with study visits for at least 4 months.

Exclusion criteria

1) Subject has known secondary cause of HTN
2) Subject has a history in the past year of persistent atrial fibrillation or clinically significant paroxysmal atrial fibrillation (clinically significant paroxysmal atrial fibrillation is defined as atrial fibrillation that in the investigators judgment would prevent the delivery of the Backbeat HTN therapy for a significant amount of the time, over 25%).
3) Subject has ejection fraction <50%
4) Subject has symptoms of heart failure of NYHA Class II or more
5) Subject has hypertrophic cardiomyopathy, restrictive cardiomyopathy or interventricular septal thickness >=15 mm
6) Subject is on dialysis
7) Subject has estimated Glomerular Filtration Rate (GFR) <30 ml/min/1.73m2
8) Subject has prior neurological events (stroke or TIA) or carotid artery disease
9) Subject has known autonomic dysfunction
10) Subject has a history of clinically significant tachyarrhythmia and is not on a stable

medical regimen
11) Subject has had previous active device-based treatment for hypertension
12) Subject has an existing implant, other than a pacemaker that needs replacing
13) Subject is pregnant or has the possibility of becoming pregnant during the conduct of the study and is not willing to use a means of contraception during the study.
14) Subject cannot or is unwilling to provide informed consent
15) Subject with average Systolic BP >190 mmHg
16) Subject is currently participating in another clinical study.

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):	04-10-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Moderato system
Registration:	No

Ethics review

Approved WMO

Date:	30-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	20-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2015
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
CCMO	NL43708.018.13