Clinical Evaluation of Safety and Effectiveness of the BackBeat Medical Moderato System in Patients with Hypertension: A Double-Blind Randomized Trial

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

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON46157

Source
ToetsingOnline

Brief title
Moderato System: A Double-Blind Randomized Trial

Condition

- Cardiac arrhythmias
- Vascular hypertensive disorders

Synonym
high blood pressure, 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, randomised, safety and effectiveness

Outcome measures

Primary outcome

Clinical Effectiveness

The primary efficacy endpoint of this study is difference of the mean change of

the

average 24-hour ambulatory systolic blood pressure (average at 3 months post

randomization visit *** average at pre-randomization Baseline visit) in the

active

treatment group (Group 1) compared to the mean change (average at 3 months post

randomization visit *** average at pre-randomization Baseline visit) in the

control group

(Group 2)

(Note: The Baseline pre-randomization 24-hour blood pressure is the mean

ambulatory

blood pressure measured at the 3 week visit during the Run-In Phase.)

Safety

The Moderato System will be considered safe if the rate of major adverse cardiac

events [including: heart failure, clinically significant arrhythmias (e.g.,

persistent or

increased atrial fibrillation, serious ventricular arrhythmias), myocardial

infarction,

stroke, heart failure and renal failure and/ or other related safety events

that result in

death] does not differ between groups through the 12 month randomized phase of

the

study..

Secondary outcome

Changes in the following parameters will be analyzed (in comparison to

pre-randomisation baseline values) and compared between groups using

descriptive statistics to provide additional information about the safety and

effectiveness of the therapy:

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*-Average day-time blood pressures from 24-hour ambulatory monitoring after 3

months of therapy

*-Average night-time blood pressures from 24-hour ambulatory monitoring after 3

months of therapy

*-Office systolic and diastolic blood pressure measurements at each time point

*-Echocardiograms: Ejection fraction, left ventricular end-diastolic and

end-systolic volumes at each timepoint

*-Blood tests: ANP, BNP, Creatinine at each timepoint

*-Overall type and rate of adverse events through 12 months of observation

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 bradyarrhythmias. Currently available devices have evolved from simple single-chamber, fixed-rate pacemakers to multichamber, 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 effectiveness of the BackBeat Moderato system.

Study design

A randomized, double-blind, multi-centric study in which patients are randomized to either a cohort that will receive active treatment with the Moderato System delivering hypertension therapy plus continued medical therapy or to a cohort that will have the Moderato System in pacemaker only mode and receive continued medical therapy.

Intervention

Standard implantation of a dual chamber pacemaker and the activation of the BackBeat-PHC therapy.

Study burden and risks

Risks associated with Moderato IPG implant (risks to which the patient would be exposed independent of participation in the study):

a. Arrhythmias, that can be serious in nature, including ventricular tachycardia, ventricular fibrillation, atrial tachycardia, atrial fibrillation
b. Damage to the heart or heart muscle
c. Perforation of the atrium or ventricle

d. Acute or delayed pericardial tamponade
e. Myocardial infarction or ischemia
f. Punctured lung cavity (pneumothorax)
g. Bleeding possibly requiring a blood transfusion
h. Infection at the site of insertion of the device that may become a systemic infection (sepsis)
i. Damage to the arteries or veins in the implant site
j. Pacemaker lead dislodgement
k. Pacemaker lead fracture
l. Loss of pacemaker sensing and/or capture that may lead to lightheadedness, fatigue, syncope or death
m. Stroke or transient ischemic attack
n. Acute heart failure or cardiogenic shock
o. Development of chronic heart failure
p. Development of pacemaker syndrome
q. Erosion of the IPG device through the skin
r. Thrombosis of veins (including the superior vena cava)
s. Damage to the heart conduction system including right bundle branch block or complete heart block
t. Fluid or blood (seroma or hematoma) collection around the pacemaker
u. Diaphragmatic and/or Phrenic Nerve stimulation
v. Pain and discomfort related to the implant that can last for several days
w. Side effects from medications used to alleviate pain and discomfort during the implant procedure
x. Device malfunction that will require replacement of device

Complications from any of the above-mentioned risks may result in death.

Potential added risks associated with delivery of PHC therapy (anticipated adverse device effects):
a. Device malfunction which may require device replacement or removal
b. Arrhythmias, including atrial fibrillation, atrial tachycardia or, less likely, ventricular tachycardia or ventricular fibrillation
c. Myocardial infarction
d. Stroke or transient ischemic attack (TIA)
e. Development of heart failure and/or significant reduction of left ventricular ejection fraction
f. Kidney dysfunction
g. Increase in heart rate due to activation of the neuro-hormonal system
h. Palpitations
i. Low blood pressure
j. Light headedness
k. Syncope
l. Development of unusual patient sensations, pain or discomfort

Since the Moderato-PHC therapy is experimental, there may be risks that are not

yet known.

Pregnant women or women who may become pregnant during the study may not participate unless they are willing to use contraceptives for the duration of the study. The physician will discuss this with the subject further. If the subject does become pregnant during the study, the study physician should be notified immediately.

There are no known risks associated with other examinations required for the study (whether or not standard of care).

Risks which are generally associated with participating in a clinical study
a. The investigational treatment may have health risks as described above.
b. The study may require more time and attention than standard treatment. The subject may need to visit the study site, take additional blood tests, stay in the hospital more than the subject would if he/ she did not participate in the study
c. It is possible that the subject will not benefit from the treatment.
d. Whether a new treatment will work cannot be known ahead of time. There is always a chance that a new treatment may not work better than a standard treatment, may not work at all, or may be harmful.
e. The treatment may cause side effects that are serious enough to require medical attention.

BENEFITS
The blood pressure may decrease as a result of the Moderato PHC therapy. The study will determine the degree to which this benefit can occur. In addition, subjects will receive the Pacemaker treatment that they need. This study may also improve or help to improve future treatment of persistent high blood pressure

Contacts

Public
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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 requires the implant or replacement of a dual chamber pacemaker or requires an upgrade from a single chamber to a dual chamber pacemaker
3) Subject has stable (for prior 6 weeks) hypertension treatment with at least 1 antihypertensive drug, which is anticipated to be able to be maintained without changes .Stable is defined as being on the same drug regimen, and the dose of each drug(s) no more than 50% reduced or 100% increased over the past 6 weeks
4) Subject has an average 24 hour ambulatory systolic blood pressure of * 130mmHg (with directly observed medical therapy, DOT) and unattended automatic average and office systolic blood pressure *140 mmHg
5) Subject is able to comply with study visits for at least 13 months (e.g., is capable and is willing to travel to/from the center for all scheduled study visits)..

Exclusion criteria

1) Subject has a known secondary cause of HTN
2) Subject with average ambulatory or office systolic BP >195 mmHg
3) Subject has permanent atrial fibrillation
4) Subject has a history of significant paroxysmal atrial fibrillation/flutter burden (defined as >25% of beats). Fibrillation/flutter burden will be determined by pacemaker interrogation (for those already having a pre-existing pacemaker) or, otherwise, by patient history.
5) Subject has ejection fraction <50%
6) Subject has symptoms of heart failure, NYHA Class II or greater
7) Subject has hypertrophic cardiomyopathy, restrictive cardiomyopathy or interventricular septal thickness *15 mm

8) Subject is on dialysis
9) Subject has estimated Glomerular Filtration Rate (GFR) <30 ml/min/1.73m2
10) Subject has prior neurological events (stroke or TIA) within the past year or an event at any prior time that has resulted in residual neurologic deficit
11) Subject has a history of significant carotid artery disease (>50% occlusion of left or right carotid artery)
12) Subject has a history of autonomic dysfunction
13) Subject has a history of clinically significant untreated ventricular tachyarrhythmia or has experienced cardiac arrest
14) Subject has had previous active device-based treatment for hypertension
15) Subject has an existing implant, other than a pacemaker that needs replacing
16) 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.
17) Subject cannot or is unwilling to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Moderato System
Registration:	No

Ethics review

Approved WMO Date:	09-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2019
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	NCT02837445
CCMO	NL56984.018.16