A Clinical Study of the Safety and Performance of the Treovance Stent-Graft with Navitel Delivery System for Patients with Infrarenal Abdominal Aortic Aneurysms

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON36578

Source
ToetsingOnline

Brief title
Advance

Condition

- Aneurysms and artery dissections

Synonym
Abdominal Aortic Aneurysm (AAA), abnormal dilatation of the abdominal aorta

Research involving
Human

Sponsors and support

Primary sponsor: Bolton Medical Espana S.L.U.
Source(s) of monetary or material Support: Bolton Medical;Inc

Intervention

Keyword: CE-mark, Infrarenal Abdominal Aortic Aneurysm, Stent-graft

Outcome measures

Primary outcome

Primary Outcome - Safety

Safety will be assessed by measurement of mortality and major morbidity.

Each of the events identified below will be evaluated compositely as well

as individually. The evaluations will be made at all follow-up intervals.

a) Death (all causes where subject death is the result of a serious and

device- or procedure-related adverse effect). Unrelated and

accidental deaths, for example a subject death due to injuries from

a car accident, would not be included in this evaluation.

b) Stroke (excludes transient ischemic attack)

c) Myocardial Infarction

d) Renal Failure requiring renal replacement therapy (excludes renal

insufficiency)

e) Respiratory Failure, defined as ventilator-dependent (excludes

chronic obstructive pulmonary disease or pulmonary

complications)

f) Paraparesis / Paraplegia

g) Bowel ischemia

h) Treated aneurysm rupture

Secondary outcome

Secondary Endpoints - Endovascular Parameters

The following endovascular measures will be assessed for preliminary performance at the follow-up intervals.

a) Delivery/Deployment: vessel access was achieved and the physician was able to insert the delivery catheter and deliver it to the treatment site and deploy the device

b) Stent-Graft Migration: longitudinal movement of all or part of the stent-graft greater than 10 mm relative to its placement as measured by imaging studies at the 1-month follow-up versus the 6-month and 12-month follow-ups

c) Stent-Graft Patency: a measure of blood flow through the vessel treated and the stent-graft

d) Stent-Graft Integrity: an assessment of stent-graft fractures, or kinking or twisting leading to occlusion or ischemiae) Endoleak: persistence of flow outside the lumen of the stent-graft but within the native aorta or adjacent vascular segment being treated by the stent-graft

f) Aneurysm Sac Size Changes: a change in the diameter (5 mm change) of the lesion relative to the measurement at 1 month versus 6-month and 12-month follow-up visit measurements

g) Limb Ischemia: resulting in limb loss

h) Vascular Access Complications: injuries to vessels as a result of

an endovascular procedure.

Study description

Background summary

An aneurysm is a dilatation in an arterial wall. The aorta is the largest vessel in the body exiting the heart and the leading source of blood for all body organs. Abdominal aortic aneurysms (AAA) are dilatations greater than 3 cm or twice the normal size in the abdominal segment of the aorta.1 Approximately 75% of all aneurysms develop in this location. Left untreated, AAAs are at risk for rupture, which typically results in death. As such, the goal of any AAA treatment should be prevention of rupture.

Study objective

The primary goal of the study is to assess the safety and performance of the Treovance Stent-Graft with Navitel Delivery System in subjects with infrarenal aortic aneurysms, specifically to evaluate if the diseased pathology can be treated with an acceptable adverse event rate and that the device performs as expected. The results of this study will support CE mark in Europe.

Secondary Objectives: The following endovascular measures/parameters will be assessed for preliminary performance at the follow-up intervals: delivery/deployment, stent-graft migration, stent-graft patency, stent-graft integrity, endoleak, aneurysm sac size changes, limb ischemia, and vascular access.

Study design

This is a prospective, multi-center, non-randomized study. A maximum of 30 patients will be required. Data from subjects enrolled in a similar trial at sites in U.S. may be used to supplement the current study data. There will be no prospective control group.

Subjects diagnosed with infrarenal aortic aneurysms enrolled into the trial will be treated with the Treovance Stent-Graft with Navitel Delivery System. Pre-procedure baseline data will be gathered as well as post-procedure assessments prior to hospital discharge and 1, 6, and 12 months post-implantation. The 6-month data from this study will be submitted to the European Regulatory Authorities to support the CE mark; subjects will continue to be monitored to 1 year post-implant when 12-month data will be reported.

Intervention

Implantation of a Treovance Stent-Graft with Navitel Delivery System

Study burden and risks

Treatment with the Treovance Stent-Graft is a procedure that poses significant risks to the subject, although these risks are not expected to be greater than with current standard of care. Although there may be risks that are not yet known or are unforeseen at this time, a summary of some of the known risks is identified below:
• Blood clots or blockage of blood flow to the brain, spinal cord or extremities which could lead to stroke, temporary or permanent paralysis, death, or amputation;
• Blood clots or blockage of blood flow to other organs (heart, lung, kidney, liver) which could lead to failure of those organs;
• Decrease or failure of kidney function which could lead to the need for dialysis;
• Leaking of blood into the lesion which could cause rupture or death;
• Rupture of a blood vessel or the aneurysm which could lead to shock, conversion to surgery, or death;
• Migration of the device which could lead to rupture of the vessel or aneurysm (if present), open surgery, or death;
• Blood loss which could lead to shock or death;
• Failure of the delivery system to properly position the device leading to the need for additional procedures or blockage of nearby vessels;
• Vessel damage during insertion of the device leading to excessive bleeding, vessel damage and possibly the need for surgery;
• Damage to the stent-graft including twisting or kinking, tearing, or breaking of the metal struts which could cause blockage of blood flow, leaking and/or rupture of the aneurysm or associated vessel, and death;
• Heart-related events including but not limited to chest pain, heart attack, high or low blood pressure;
• Lung-related events including but not limited to breathing difficulty and pneumonia;
• Impotence / loss of sexual functioning;
• Infection, which could lead to whole-body infection or death;
• The potential need to convert to surgery; and
• Death
There are other health risks and discomforts associated with the testing that the subjects will undergo before and after their procedure including but not limited to bruising during blood collection, pain and bruising at the access site, and radiation exposure during imaging procedures.

Mitigation of Risks
Bolton Medical, Inc. has taken great care in the design and evaluation of the

Treovance Stent-Graft to ensure that such risks are minimized to the extent possible. From a design standpoint, the Treovance Stent-Graft is constructed with materials having an established history of use in medical applications. In particular, nitinol is used in a variety of implantable devices, including stent-grafts. Polyester vascular graft fabric is currently used in surgical repair of aneurysms. The materials and processes used were selected also for their superior performance and durability. Most notably, the nitinol stents are processed to ensure optimal self-expansion and fatigue endurance properties that allow the device to conform well to the vessel wall and establish a secure seal. Furthermore, the surface of these stents is polished to maximize fatigue endurance by minimizing the potential for cracking and other surface imperfections that can lead to fatigue fracture. Another safeguard against risk is the procedure for stentgraft selection to ensure that the most appropriate-sized device is implanted and therefore reduces the risk of endoleaks, migration, and even ruptures. The controlled deployment mechanism of the delivery system and the two-stage design allows for an easier trackability and placement. These controls mitigate the potential for vessel trauma and misplacement of the stent-graft.
The studies described previously have shown favorable performance of the system. In these studies, the device was subjected to simulated conditions of use as well as worst-case conditions of use. In vivo preclinical animal studies conducted in sheep validated the in vitro results. Delivery and deployment was successful and in vivo visualization was favorable. Furthermore, the stent-graft maintained patency and integrity in situ at the 26-week evaluation in the ovine model.

Benefits to Subjects
Patients who participate in this trial may benefit by having their abdominal aortic aneurysms treated with a less invasive procedure than open surgical repair. The amount of discomfort and scarring experienced should be less than for open repair. The time required for the patient to spend in intensive care and the entire hospital stay should be less than for open repair. Recovery time should be less than with open repair.

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

a.) Subject must be between the ages of 18 and 85.
b.) Subject must be diagnosed with an infrarenal abdominal aortic aneurysm (AAA), with or without iliac artery involvement, by CT with contrast performed within 3 months of planned implant procedure.
c.) Subject must have an infrarenal AAA that
i. is > 4.5 cm in diameter for males, or > 4.0 cm in diameter for females, or
ii. has increased in diameter by 0.5 cm in the last 6 months
d.) Subject must have
i. infrarenal landing neck length of 10 mm or greater and an angle of less than 60 degrees relative to the long axis of the aneurysm (centerline at lowest renal to centerline at bifurcation) and a suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an inside diameter of 17 mm - 32 mm, or
ii. infrarenal landing neck length of 15 mm or greater and an angle of between 60 and 75 degrees relative to the long axis of the aneurysm and a suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an inside diameter of 16 mm-30 mm
e.) Subject*s infrarenal landing neck must
i. have no significant calcification or thrombus formation, and
ii. meet the vessel size requirements specified in the instructions for use (IFU) for the corresponding devices
f.) Subject must have lowest renal artery at least 9 cm from the aortic bifurcation
g.) Subject must have a distal iliac landing neck with
i. an inside diameter of 7 mm - 13 mm and a length of at least 10 mm, or
ii. an inside diameter of >13 mm - 20 mm and a length of at least 15 mm
h.) Subject*s distal iliac landing neck must

i. have no significant calcification or thrombus formation, and
ii. meet the vessel size requirements specified for the corresponding devices in the IFU
i.) Subject must have a total treatment length of at least 13 cm
j.) Subject must be willing and able to comply with 1-month, 6-month, and 12-month follow-up visits.
k.) Subject must have adequate vascular access (e.g., patent iliac or femoral arteries) for introduction of the Navitel Delivery System which is 18F (6 mm) or 19F (6.3 mm) outer diameter based on size of device used. Alternatively, subject*s anatomy is suitable for creation of an iliac conduit.
l.) Subject or Legally Authorized Representative (LAR) must agree to sign Informed Consent Form

Exclusion criteria

Subjects may not enroll into the study if any of the following apply:
a.) Subject is pregnant or lactating
b.) Subject has a dissection, ruptured aneurysm, or symptomatic aneurysm (as determined by treating physician)
c.) Subject has a patent inferior mesenteric artery that cannot be sacrificed and an occluded or stenotic celiac and/or superior mesenteric artery
d.) Implant procedure as planned does not allow for at least one patent hypogastric artery left intact, unless both are occluded on pre-op imaging
e.) Subject has a lesion that cannot be crossed by a guide wire
f.) Proximal neck cannot increase by more than 10% over 15 mm; i.e., no trapezoidal necks
g.) Subject has severe untreated coronary artery disease and/or unstable angina, significant areas of myocardium at risk (based on coronary angiogram or radionuclide scans), left ventricular ejection fraction < 20%, or recent diagnosis of CHF
h.) Subject has had a stroke or MI within 6 months of the planned treatment date
i.) Subject has chronic obstructive pulmonary disease requiring routine need for oxygen therapy outside the hospital setting (e.g., daily or nightly home use)
j.) Subject has an active systemic infection or is suspected of having an active systemic infection (e.g., AIDS/HIV, sepsis)
k.) Subject is morbidly obese (more than 100% over the ideal body weight or as defined by institutional standards) or has other clinical conditions that severely compromise or impair x-ray visualization of the aorta
l.) Subject has connective tissue disease (e.g., Marfan*s syndrome)
m.) Subject has a mycotic aneurysm
n.) Subject has significant or circumferential mural thrombus in the proximal aortic neck
o.) Subject has a blood coagulation disorder or bleeding diathesis the treatment for which cannot be suspended pre- and post-repair
p.) Subject is in acute or chronic renal failure (creatinine > 2.5 mg/dL)
q.) Subject has less than two-year life expectancy as evidenced by factors prohibiting major medical intervention (e.g., presence of malignancy, severe cardiopulmonary disease, etc.)
r.) Subject is participating in another research study, has received investigational study drug within 30 days of planned procedure, or has received an investigational device within one

year of planned procedure.
s.) Subject is confronted with other medical, social or psychological issues that the investigator believes may interfere with study treatment or follow-up. These reasons must be documented. An example may include adherence to a theological or personal doctrine with aversion or opposition to blood transfusion.
t.) Subject has had a prior AAA repair (endovascular or surgical)
u.) Subject has an untreatable allergy or sensitivity to contrast media, nitinol/nickel, or polyester
v.) Subject has undergone other major surgical or medical intervention within 45 days of the planned procedure or is planning to undergo other major surgical or medical intervention within 45 days post implantation (e.g., CABG, organ transplantation, renal stenting, etc.)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-11-2010
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Generic name:	Treovance Stent-Graft with Navitel Delivery System
Registration:	No

Ethics review

Approved WMO

Date:	04-04-2011
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-11-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34037.078.10