Clinical Study to Evaluate the Safety and Performance of MANTA Vascular Closure Device

Published: 22-06-2015
Last updated: 16-04-2024

To evaluate the safety and performance of MANTA in achieving hemostasis in femoral arterial access sites in patients undergoing percutaneous transcatheter interventional procedures using a 10-18F procedure sheath for purposes of obtaining a CE Mark...

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

Summary

ID

NL-OMON42594

Source
ToetsingOnline

Brief title
MANTA PSD-051

Condition

- Other condition
- Heart failures
- Vascular therapeutic procedures

Synonym
Cardiac disease; Vascular intervention

Health condition

Aandoeningen aan de hartklep

Research involving

Human

Sponsors and support

Primary sponsor: Essential Medical Inc.
Source(s) of monetary or material Support: Door de sponsor - Essential Medical;Inc.

Intervention

Keyword: Arteriotomy closure, Hemostasis, Percutaneous transcatheter intervention

Outcome measures

Primary outcome

Primary Safety Endpoint: The rate of Major Complications, composite endpoint

that includes any of the following adverse events:

* Access site-related bleeding requiring blood transfusion or vascular repair

* Vascular injury requiring repair (e.g. perforation dissection, arterio-venous

fistula, retroperitoneal bleed, pseudoaneurysm)

* Femoral artery stenosis at the access site requiring intervention

* New ipsilateral lower extremity ischemia causing a threat to the viability of

the limb

* Access site-related infection requiring intravenous antibiotics and/or

extended hospitalization

* New onset access site-related neuropathy in the ipsilateral lower extremity

requiring surgical repair

* Permanent access site-related nerve injury (lasting>30 days)

. Primary Effectiveness Endpoint: The rate of Hemostasis Success

Secondary outcome

Secondary Safety Endpoint: The rate of Minor Complications within 30±7 days following the procedure, composite endpoint that includes any of the following adverse events:

* Access site-related bleeding requiring > 30 minutes to achieve hemostasis
* Access site-related hematoma > 6 cm
* Late access site-related bleeding (following hospital discharge)
* Ipsilateral lower extremity arterial emboli
* Ipsilateral deep vein thrombosis
* Access site-related vessel laceration
* Access site wound dehiscence
* Localized access site infection treated with intramuscular or oral antibiotics
* Arteriovenous fistula not requiring treatment
* Pseudoaneurysm requiring thrombin injection or fibrin adhesive injection
* Pseudoaneurysm not requiring treatment
* New onset access site-related neuropathy in the ipsilateral lower extremity not requiring surgical repair
* Ipsilateral pedal pulse diminished by two grades or transiently lost
* Any other adverse event that is definitely or probably device-related or access-site related

Secondary Effectiveness Endpoints: Time to Hemostasis (The elapsed time between MANTA deployment (withdrawal of sheath from artery) and first observed and confirmed arterial hemostasis (no or minimal subcutaneous oozing and the absence of expanding or developing hematoma)), Time to Ambulation (The elapsed

time between MANTA deployment (withdrawal of sheath from artery) and when ambulation is achieved (patient standing and walking at least 20 feet without re-bleeding)) and Treatment Success (MANTA delivery system successfully deployed and hemostasis achieved by MANTA alone or with adjunctive compression (manual or mechanical) with freedom from Major Complications).

Study description

Background summary

The advent of percutaneous cardiac and peripheral procedures performed through large bore arteriotomies, such as transcatheter aortic valve replacement (TAVR), endovascular aneurysm repair (EVAR), and balloon aortic valvuloplasty (BAV), demonstrates a need for a safe and effective vascular closure device to replace the current standard of care of surgical cut-down/repair or use of multiple small bore suture-mediated closure devices that were not designed for large bore punctures.

Study objective

To evaluate the safety and performance of MANTA in achieving hemostasis in femoral arterial access sites in patients undergoing percutaneous transcatheter interventional procedures using a 10-18F procedure sheath for purposes of obtaining a CE Mark in the EU.

Study design

Prospective, multi-center, open-label, single-arm clinical investigation

Intervention

In stead of conventional closure techniques, the MANTA 14F or 18F is used (dependent on size of sheath used, determination of physician).

Study burden and risks

Use of the MANTA device carries risk from procedural error, inherent use hazards, and device failure. Essential Medical, Inc. has taken measures to ensure the device is designed, manufactured and tested appropriately to

mitigate and control these risks through systematic risk analysis, in-process controls and final inspection, labeling, instructions for use, and post-market surveillance. As a result, the residual risk is as low as possible.

Risks from the clinical study itself are negligible. The only non-standard test required by the study protocol is duplex ultrasound of the femoral artery at baseline, prior to discharge and at follow-up. Ultrasound is a non-invasive standard diagnostic test that carries almost no risk, apart from the possibility of minimal patient discomfort from the pressure of the transducer. All of the other study procedures are standard of care for interventional peripheral and cardiac procedures.

In conclusion, the potential benefits of the MANTA device are expected to outweigh the aforementioned mitigated risks and exceed or meet the performance of current treatment methods, and the study itself carries almost no additional risk. Therefore, the clinical study is justified by the risk/benefit ratio

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

* Candidate for non-emergent transcatheter interventional procedure via a 10-18F femoral sheath (e.g., transcatheter aortic valve replacement [TAVR], balloon aortic valvuloplasty [BAV], abdominal aortic aneurysm [AAA] stent-graft placement)
* Eligible for sheath removal in the catheterization lab
* Age *18 years
* Understand and sign the study specific written informed consent form
* Able and willing to fulfill the follow-up requirements
* In the Investigator*s opinion, the patient is suitable for the MANTA vascular closure device, conventional hemostasis techniques and participation in an investigational trial
* Patients of childbearing age with Negative Pregnancy Test within 7 days of procedure

Exclusion criteria

Baseline exclusions:
* Patients who are known to be pregnant or lactating
* Patients who are immunocompromised or with pre-existing autoimmune disease
* Patients who have a systemic infection or a local infection at or near the access site
* Patients requiring a re-puncture at a site previously punctured within 48 hours
* Patients with significant anemia (hemoglobin <6.5 mmol/L, Hematocrit<30)
* Patients who are morbidly obese or cachectic (BMI >40 or <20)
* Patients with Systolic Blood Pressure >180 mmHg, unless Systolic Pressure can be lowered by pharmacological agents prior to closure
* Patients who are currently participating in another clinical trial of an investigational device or drug that has not concluded the follow-up period
* Patients in whom an antegrade puncture is performed or planned
* Patients with a known bleeding disorder including thrombocytopenia (platelet count <100 x 10^9/L), thrombasthenia, hemophilia, or von Willebrand*s disease
* Patients with a femoral artery <6 mm in diameter, femoral artery stenosis resulting in a vessel diameter <6 mm, or patients with severe peripheral vascular disease
* Common femoral artery with fluoroscopically visible calcium, as determined by Angio CT, precluding safe access in the opinion of the investigator.
* Patients with allergy to bovine materials, collagen and/or collagen products, or polyglycolic or polyactic acid polymers
* Patients who cannot adhere to or complete the investigational protocol for any reason including but not limited to geographical residence or life threatening disease
* Patients punctured through a vascular graft
* Patients with known allergy to stainless steel or nickel
* Patients who have acute ST-elevation MI within 48 hours prior to the procedure

* Patients with unilateral or bilateral lower extremity amputation
* Patients with renal insufficiency (serum creatinine > 2,5mg/dl)
* Patients undergoing therapeutic thrombolysis
* Patients who are unable to ambulate at baseline (necessary to determine time-to-ambulation)
* Patients undergoing an interventional procedure whom are being treated with warfarin
* Patients requiring a continuous oral anticoagulation therapy or patients with INR >1.8. Patients may be admitted into the study if oral anticoagulation therapy is stopped prior to procedure and resumed after the procedure.;Intra-procedure exclusions:
* Patients with puncture sites believed to be in the profunda femoris, superficial femoral artery, or at the bifurcation of the arteries
* Femoral arteries that are suspected to have experienced a back wall puncture or that underwent > one (1) arterial puncture during the catheterization procedure
* Patients in whom the puncture site is located above the most inferior border of the epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed
* Patients in whom bacterial contamination of the procedure sheath or surrounding tissues may have occurred as this may result in infection
* Patients having a complication(s) at the femoral artery access site pre-sheath removal including hematoma, pseudoaneurysm, or arterio-venous fistula
* Patients whose ACT is >250 seconds prior to removal of the guiding catheter
* Patients with marked turtuosity of the femoral or iliac artery

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):	22-07-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	MANTA 14F and 18F Vascular Closure Device
Registration:	No

Ethics review

Approved WMO Date:	22-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2016
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	NL52577.078.15

Study results

Date completed: 22-03-2016

Actual enrolment: 35

Summary results
Trial is onging in other countries