First-in-Human for Fiber Optic RealShape (FORS)

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The objective of this study is to assess performance of navigation in the arterial tree by using catheters and guidewires that are enabled with FORS-based guidance as add-on to X ray imaging, in aortic and peripheral endovascular procedures.

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

Summary

ID

NL-OMON46231

Source
ToetsingOnline

Brief title
FORS FIRST

Condition

- Other condition
- Aneurysms and artery dissections

Synonym
Aneurysm, Peripheral Artery Disease

Health condition

bloedvataandoeningen van aorta en lager> arteriosclerose, stenose, vaatinsufficiëntie en necrose

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips Medical Systems

Intervention

Keyword: Aneurysm, Peripheral artery disease, Radiation

Outcome measures

Primary outcome

Main study endpoint is the technical success of well-defined navigation tasks during the endovascular procedure. Also, qualitative scores will be collected from the operator on performance parameters of FORS-enabled image guidance as add-on to X ray.

Secondary outcome

Additional study endpoints are: procedural technical success, *ski-to-skin* procedure time, cumulative radiation dose (for patient, for each staff member), cumulative fluoroscopy time, navigation task time, navigation radiation dose (for patient, for each staff member), navigation fluoroscopy time, cumulative contrast agent dosevolume.

Study description

Background summary

In the past years, the endovascular approach has become the standard treatment option for an increasing portion of patients affected by aortic and/or iliac aneurysms, as well as for patients with peripheral occlusive disease in lower limbs. The gold standard imaging modality for peripheral endovascular procedures is X ray imaging. The availability of new and improved treatment devices, which can treat increasingly difficult anatomies, has also resulted in increasingly complex procedures, with long procedural times, high radiation

exposure and large contrast agent volume. This calls for development of new tools to make complex procedures faster, easier to perform, and feasible with less radiation exposure and lower contrast dose. Philips has developed the AltaTrack device, which provides a more intuitive visualization of both the anatomy and of the in-patient devices. The 3D real time visualization of the in-body instruments is obtained by employing the light-based Fiber Optic RealShape (FORS) technology. The FORS-enabled catheters and guidewires are entirely equivalent in mechanical behaviour and radiopacity to standard angiographic catheters and guidewires; in addition, they provide an X ray-free 3D visualization of the medical instrument in the patient*s body. The use of this technology for guidance in navigation during peripheral endovascular procedures can potentially lead to reduced radiation exposure, for patients and staff, reduced contrast dose and shorter procedure times. The AltaTrack device is a non-CE marked device and has never been tested in human subjects. This Study is the first-in-human trial to evaluate the use of such a device.

Study objective

The objective of this study is to assess performance of navigation in the arterial tree by using catheters and guidewires that are enabled with FORS-based guidance as add-on to X ray imaging, in aortic and peripheral endovascular procedures.

Study design

This is a single center, open label, single arm, and prospective interventional trial, in subjects that undergo elective aortic or peripheral endovascular treatment. The study will include up to 20 subjects.

Intervention

All study subjects will undergo patient care as in the current practice, pre-as well as post-treatment. During the treatment intervention, all steps of the intervention will be executed as in current practice except for the navigation part. During navigation to reach the area to treat, instead of using catheters and guidewires, which only rely on X ray for visualization, the FORS-enabled catheters and guidewires will be used, thereby providing FORS-based image guidance in addition to X ray.

Study burden and risks

In this study, the risk and burden to the subjects have been judged by several physicians to be minimal. The subjects involved will be scheduled for standard endovascular treatment and the use of the investigational device does not represent higher risk or burden compared to the use of devices commercially available and employed in the standard of practice.

On the other hand, the investigational device provides more intuitive information to the operator on the in-body location of the device during the intervention, thereby, potentially making the navigation step of the intervention easier to perform. As a result, procedure times may become shorter. In addition, the use of the investigational device may lead to a reduction of radiation exposure to the patient (and to the operator), and a reduction of contrast agent volume. Therefore, the outcome of this study may be potentially beneficial for all patients that will be scheduled for endovascular treatment in the future.

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

• Age > 18 years.

• Willingness to sign informed consent.
• Scheduled for elective endovascular procedure either for stenotic or aneurysmatic pathology
• Anatomical conformation suitable for the investigational medical devices (5.5 F 80cm Cobra C2 catheter, and/or 5.5F 80cm Berenstein catheter, and a 0.035* 120cm floppy guidewire)

Exclusion criteria

•Intolerance to contrast media.
•Emergency procedure.
•Current participation in a concurrent trial that may confound study results.
•Subjects unwilling or unable to comply with the protocol.
•Subjects unable to understand verbal and/or written informed consent.

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):	31-07-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	AltaTrack system;including catheters;guidewires and software
Registration:	No

Ethics review

Approved WMO Date:	11-07-2018
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28817
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65894.041.18
OMON	NL-OMON28817