FORS FIRST

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28817

Source
NTR

Brief title
FORS FIRST

Health condition

abdominal aortic aneurysm (AAA), iliac aneurysms (IA), stenotic lesions of the iliac artery or Superficial Femoral Artery (SFA).

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Technical success of navigation

Secondary outcome

-Procedural technical success (defined as successful completion of the procedure)

-Type of procedure

-Cumulative Air Kerma (AK)

-Cumulative Dose Air Product (DAP)

-Cumulative Digital Subtraction Angiography (DSA) dose

-Cumulative fluoroscopy dose

-Cumulative fluoroscopy time

-Cumulative contrast agent volume

-Cumulative staff dose for each staff member (operator 1, operator 2, sterile nurse)

-Radiation dose XperCT, if applicable

-“Skin-to-skin” procedure time

-Time to perform each navigation task

-AK of each navigation task

-DAP of each navigation task

-Fluoroscopy time of each navigation task

-Staff dose of each staff member for each navigation task (operator 1, operator 2, sterile nurse)

-Number of re-registrations of CTA

-Number of re-registrations of FORS-enabled device visualization

-Number of bail outs (switch to X ray-guidance only) during navigation tasks and reason for it

-Type of treatment device (type, brand)

-Serious Adverse Device Effects (SADEs)

Study description

Background summary

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 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 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 (FIH) 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 Fiber Optic RealShape (FORS)-enabled catheters and guidewires, thereby using FORS-based guidance as add-on to X ray imaging, in aortic and peripheral endovascular procedures. Performance, therefore, concerns two aspects: 1) performance of the FORS-enabled devices, and 2) performance of the FORS-based image guidance, as add on to X ray. Hence, performance of the Philips AltaTrack investigational device will be assessed through: 1) technical success of navigation in the arterial tree by using the FORS-enabled catheters and guidewires, and 2) qualitative judgement by the operator on the usefulness of FORS-based image guidance.

Study design

not applicable

Intervention

-aortic endovascular intervention

-peripheral endovascular intervention

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Eligibility criteria

Inclusion criteria

-Age > 18 years

-Willingness to sign the 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

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2018
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	14-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46231
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7074
NTR-old	NTR7272
CCMO	NL65894.041.18
OMON	NL-OMON46231

Study results