

FORS FIRST

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28817

Bron

NTR

Verkorte titel

FORS FIRST

Aandoening

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

Ondersteuning

Primaire sponsor: Philips Healthcare

Overige ondersteuning: Philips Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Technical success of navigation

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

not applicable

Onderzoeksproduct en/of interventie

-aortic endovascular intervention

-peripheral endovascular intervention

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	15-07-2018
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	14-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46231
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten