Postoperative flow prediction after creation of a vasculair access for hemodialysis with the aid of a computer simulation model.

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20401

Bron NTR

NIK

Verkorte titel AVF model

Aandoening

1. Non-maturation of an arteriovenous fistula;

2. Flow prediction;

3. Computer simulation model.

Ondersteuning

Primaire sponsor: 1. University of Technology Eindhoven, Department of Biomedical Engineering;

2. University Hospital Maastricht, Department of Surgery.
Overige ondersteuning: Fund=initiator 2=sponsor

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 1. A model that is able to predict the patient-specific postoperative flow with a maximum deviation of 10% compared to the measured postoperative flow;

- 2. A model for postoperative flow prediction that is clinically evaluated for 60 patients;

- 3. A model that is able to predict hypoperfusion;

- 4. A model for hypoperfusion that is clinically evaluated for 60 patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Hemodialysis dependent patients, suffering from end-stage renal disease, need a wellfunctioning vascular access to connect them with the dialyzer. Usually, the vascular access is surgically created by making a connection between an artery and a vein (arteriovenous fistula=AVF). Due to the low resistance leak created and the high arterial-venous pressure difference, vessel adaptation (remodeling) would occur with an enormous increase in blood flow and proximal vessel dilatation. As a results, proper cannulation and the connection with the dialyzer becomes possible. The use of an autogenous wrist AVF (between the radial artery and cephalic vein) is preferred due to its better long-term patency and its smaller complication rate compared to more proximal AVF's and grafts. However, a significant amount of wrist AVF's fail directly after the surgical intervention due to thrombosis and/or insufficient vessel remodeling.

Unless the fact that all those patients are selected based on preoperative diagnostics (duplex, physical examination and CE-MRA), 30% of all newly created wrist AVF's fail within six weeks after surgery and are useless for hemodialysis. For the planning of the type of vascular access for each individual patient, it is very important to preoperatively predict the postoperative flow increase and vessel remodeling. When insufficient vessel remodeling is likely, based on preoperative diagnostics, another type of vascular access can be chosen. The hypothesis is that the amount of failing AVF's can be reduced, if the blood flow increase through the AVF can be better predicted with the available preoperative diagnostics, since vessel adaptation is related to blood flow increase. A patient-specific computer simulation model, based on preoperative MRA and duplex data, can possibly give insight in the postoperative blood flow increase and failure incidence for different fistula configurations. The big advantage of the computer model is that the combination of the different factors, influencing AVF failure, like vessel diameters, vessel compliances and accessory veins, can be varied and examined.

Doel van het onderzoek

It is generally accepted that the early-postoperative flow increase is indicative for successful maturation of an autologous arteriovenous fistula. Our hypothesis is that a patient-specific computer simulation model should be able to predict this postoperative flow before surgery. Ultimately, such a model could be used for surgical planning.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All participants in this study will receive both pre- and postoperatively a CE-MRA examination, a duplex examination (only preoperatively) and pressure measurements (radial artery and finger). The duration of all examinations in total is 4 hours (two hours preoperatively and two hours postoperatively). All measurements are performed when the patient is already in the hospital for hemodialysis, for another examination not related to this study or when they are in the hospital one day before surgery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pre-dialysis patients with a detoriation of kidney function and an expected start with hemodialysis within three months and patients that are approved to receive a vascular access based on preoperative diagnostics;

2. Dialysis patients for which it becomes necessary to create a new vascular access because the old vascular access has become useless for proper hemodialysis. In addition, the patients should be approved to receive a vascular access in the contralateral arm based on preoperative diagnostics;

3. Only patients with an age of 18 years and older are included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Standard contra-indications for CE-MRA (ferromagnetic implants that can possibly move, pacemakers or claustrofobia). For patients with such implants, we use Shellock's most updated manual to determine if we can make the scan or not;

2. Possible or proved over-sensitivity for the Gadolinium containing contrast agent;

3. Patients younger than 18 years old.

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

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Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	60
Туре:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL664
NTR-old	NTR1169
Ander register	Eindhoven University of Technology/University Hospital Maastricht : incomplete
ISRCTN	Wordt niet aangevraagd/Observational study

Resultaten

Samenvatting resultaten

N/A

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