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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20401

Source
Nationaal Trial Register

Brief title
AVF model

Health condition

1. Non-maturation of an arteriovenous fistula;

2. Flow prediction;

3. Computer simulation model.

Sponsors and support

Primary sponsor: 1. University of Technology Eindhoven, Department of Biomedical Engineering;
2. University Hospital Maastricht, Department of Surgery.
Source(s) of monetary or material Support: Fund=initiator 2=sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Pilot study:

1. A measurement protocol to determine the vessel compliances by using ultrasound;

2. A measurement protocol to determine the patient's geometry by using CE-MRA.

Study description

Background summary

Hemodialysis dependent patients, suffering from end-stage renal disease, need a well-functioning 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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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

Study results

Summary results
N/A