Personalised hemodynamic modeling of arteriovenous grafts

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(1) To develop patient-specific hemodynamic models of arteriovenous grafts at multiple time points after surgery, thereby including venous outflow stenosis; (2) to determine the critical stenosis severity at which the arteriovenous graft is at risk...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON54588

Source
ToetsingOnline

Brief title
Hemodynamic modeling of arteriovenous grafts

Condition

- Renal disorders (excl nephropathies)
- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
Arteriovenous graft stenosis; vascular access stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arteriovenous grafts, Computational fluid dynamics, Hemodialysis, Stenosis

Outcome measures

Primary outcome

We will provide a descriptive evaluation of blood flow patterns and derived parameters in our hemodynamic models, which is common practice in studies on computational fluid dynamics simulations in vascular access. The secondary study parameters are the degree of stenosis at which the graft is at risk of thrombosis according to the computational fluid dynamics model, and the associations between hemodynamic parameters and future stenosis development.

Secondary outcome

Not applicable.

Study description

Background summary

The most common complication of arteriovenous grafts for hemodialysis treatment is stenosis at the venous outflow. Based on the idea that stenosis will lead to thrombosis, it is common practice to correct hemodynamically significant stenoses. However, randomized controlled trials have shown that these preemptive interventions do not prevent graft thrombosis or access failure. Personalised computational fluid dynamics modeling of arteriovenous grafts gives insight into the local hemodynamics of arteriovenous grafts. These computer simulations may eventually be helpful to predict the site of stenosis and the risk of thrombosis in the vascular access.

Study objective

(1) To develop patient-specific hemodynamic models of arteriovenous grafts at multiple time points after surgery, thereby including venous outflow stenosis; (2) to determine the critical stenosis severity at which the arteriovenous graft is at risk of thrombosis; and (3) to study associations between

hemodynamic parameters and future stenosis development.

Study design

Observational cohort study with a follow-up period of 1 year.

Study burden and risks

Patients will receive 2 MRI scans and 10 duplex ultrasound examinations within the 1-year follow-up period. We will schedule the diagnostic studies before or after dialysis sessions to reduce patient discomfort. Usual clinical practice would be to have 5 duplex ultrasound examinations in this time period. There are no risks or benefits associated with participating in the study.

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

- Patients receiving vascular access surgery at Maastricht UMC+
- Patients receiving a first ipsilateral upper arm arteriovenous graft
(straight and loop configurations and different graft materials can be included)
- Patients 18 years and older and mentally competent

Exclusion criteria

- Patients with a life expectancy of less than one year
- Patients with central venous stenosis at baseline
- Patients with contraindications for magnetic resonance imaging (MRI)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	20-06-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL67174.068.19