Randomized-controlled clinical trial for the evaluation of the efficacy of computational simulation for the planning of vascular access surgery in hemodialysis patients

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To evaluate the efficacy of computational simulation for the planning of vascular access surgery in hemodialysis patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON44805

Source
ToetsingOnline

Brief title
ShuntSimulationStudy (3S)

Condition

- Nephropathies
- Vascular therapeutic procedures

Synonym
Non-maturation, primary failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: Arterivenous fistula (AVF), Computational simulation, Non-maturation

Outcome measures

Primary outcome

Occurrence of non-maturation. Yes/no; proportion in both study groups.

Secondary outcome

Occurrence of high-flow complications (i.e., heart failure, distal ischemia).

Yes/no, proportions in both study groups.

Duration of primary patency.

Influence of comorbidities and medication on the outcome of AVF creation.

Degree of agreement between predicted and measured postoperative flow.

AVF functionality and time-to.

Study description

Background summary

Patients suffering from end-stage renal disease (ESRD) are dependent on renal replacement therapy (dialysis). The majority of dialysis is facilitated by hemodialysis. For hemodialysis a vascular access is necessary, preferable an arteriovenous fistel (AVF) in which a vein is directly anastomosed to an artery. In order to use the AVF for hemodialysis three criteria have to be met; the minimal flow over the AVF is 600 mL/min, the diameter is at least 6 mm, and the AVF is located less than 6 mm under the skin. Unfortunately, approximately half of the patients (50%) are confronted with an AVF that does not meet these criteria; the so called non-maturation or primary failure. In case of non-maturation the AVF is not only unusable for dialysis, but also requires reinterventions on short- and long-term. Firstly to mature the AVF, and

secondly, when the AVF is matured, to keep the vascular access.
Using a computational simulation postoperative flow can be predicted. Based on patient-specific duplex measurements, the model can calculate the flow that can be expected following vascular access surgery for all AVF configurations; fore- or upper arm. These calculations lead to an advice which configuration is indicated; a flow that exceeds 600 mL/min, leading to maturation. Potentially the aforementioned 50% of non-maturation can be reduced. The patient then has an adequate vascular access and reinterventions are adverted, resulting in a decrease of costs, hospital demand, and an increase of the patients' quality of life.
When the expected reduction of non-maturation is confirmed, the computational tool can be offered to other hospitals.

Study objective

To evaluate the efficacy of computational simulation for the planning of vascular access surgery in hemodialysis patients.

Study design

Randomized-controlled clinical trial. In the intervention group the vascular surgeon receives an overview of relevant patient characteristics (including duplex measurements) and an advice which AVF-configuration (fore- or upper arm) is indicated. In the control group, the vascular surgeon only receives the overview.

Intervention

Randomization for the type of surgical vascular access creation (fore- or upper arm AVF).

Study burden and risks

Additional burden for this study is approximately one hour. This hour consists of additional non-invasive duplex measurements, necessary for reliable predictions by the computational tool. It is, however, possible that local preoperative duplex protocol already contains these measurements. Then the burden is practically absent.
Based on previous research there are no expected risks that are directly related to the computational tool.

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

Incident patients that enter the pre-dialysis program because of end-stage renal failure and need for vascular access.
Permanent dialysis patients in need of a new VA in the contralateral arm because of a previous failed access.

Exclusion criteria

Patients with contraindications for creation of an autologous AVF (skin infection, ischemia, heart failure).
Previous vascular access in ipsilateral arm.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-06-2015
Enrollment:	236
Type:	Actual

Medical products/devices used

Generic name:	Computational model for shunt simulation
Registration:	No

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-11-2015
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-08-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2017
Application type:	Amendment
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
ClinicalTrials.gov	NCT02453412
CCMO	NL51610.068.14