Brachiocephalic arteriovenous fistulae: two different techniques of bloodless surgery and their effect on fistula stenosis.

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The primary aim of this study was to compare bloodless surgery using vascular clamps and a tourniquet with respect to the development of an anatomical or hemodynamic significant stenosis in patients with a brachiocephalic or radiocephalic AVF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46284

Source
ToetsingOnline

Brief title
AVF: techniques of bloodless surgery and the effect on stenosis.

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
abnormal narrowing in bloodvessel, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Onderzoek wordt niet gefinancierd. (Derde geldstroom aangevinkt aangezien zonder vink formulier niet definitief kan worden gemaakt)

Intervention

Keyword: Arteriovenous fistula, Bloodless surgery, Stenosis

Outcome measures

Primary outcome

Duplex Ultrasonography ± 6 weeks postoperative: prevalence of anatomical or hemodynamic significant stenosis and the area of the stenosis in the arterial inflow, anastomosis or venous outflow region. - significant anatomical stenosis: a decrease >50% of vessel diameter compared to the immediately upstream or downstream 'normal' vessel - significant hemodynamically arterial inflow or venous outflow stenosis: Peak Systolic Velocity Ratio 2 or greater. - significant hemodynamically anastomotic stenosis: Peak Systolic Velocity Ratio 3 or greater.

Secondary outcome

To compare preoperative factors between groups: - Demographic characteristics: age, gender, length, weight, BMI, smoking, use of drugs or alcohol, dominant arm, race. - Co-morbidity: indication AVF, Diabetes Mellitus, hypertension, hypercholesterolemy, peripheral arterial disease, etc. - Use of medication - Laboratory results. To compare operative factors between groups: - Duration of operation, duration of bloodless surgery, complications. To compare postoperative outcomes between groups: - Complications: death, hematoma, stenosis, occlusion, decrease of flow, bleeding, infection, pseudoaneurysm,

accessory veins, steal syndrome, non-maturation, cardiac en pulmonary

complications, reintervention. - Primary patency - Secondary patency

Study description

Background summary

Patients with a chronic kidney disease who opt for hemodialysis, needs a well-functioning hemodialysis access. The autologous arteriovenous fistula (AVF) is recognized as the golden standard of dialysis access(1). Unfortunately a great number of the AVFs fail to mature, and therefore cannot be used for dialysis. A significant stenosis is a major cause of nonmaturing AVFs (2,3). Remarkable are the stenoses that seem to develop in the venous outflow tract where the vascular clamp was located during surgery. The primary aim of this study was to compare bloodless surgery using vascular clamps and a tourniquet with respect to the development of hemodynamic or anatomical significant stenosis in patients with a brachiocephalic or radiocephalic AVF.

Study objective

The primary aim of this study was to compare bloodless surgery using vascular clamps and a tourniquet with respect to the development of an anatomical or hemodynamic significant stenosis in patients with a brachiocephalic or radiocephalic AVF.

Study design

A randomized controlled trial. Patients will be randomized to the use of a tourniquet or vascular clamps to obtain a bloodless field during arteriovenous fistula surgery. An interim analysis will be done after the inclusion of 52 patients.

Intervention

Intervention: the use of a tourniquet to obtain a bloodless field during arteriovenous fistula surgery. Comparator: the use of vascular clamps to obtain a bloodless field during arteriovenous fistula surgery.

Study burden and risks

Patients will, except the informed consent procedure, not undergo extra exams for study purposes.

Contacts

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HagaZiekenhuis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Mentally competent
- Written informed consent
- Age 18 years and older
- Indication for brachiocephalic AVF in HagaZiekenhuis
- Patient is able to complete the follow-up evaluation

Exclusion criteria

Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2016
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-04-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-08-2016
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-07-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	03-12-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54827.098.15