# 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,

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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**

#### **Public**

HagaZiekenhuis

Leyweg 275 Den Haag 2545CH NL

**Scientific** 

HagaZiekenhuis

Leyweg 275 Den Haag 2545CH NL

## **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)

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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