ELBA Trial
Ellbow arteriovenous fistula versus Basilic Vein transposition for chronic hemodialysis.

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The main objective of this study is to show that the basilic vein transposition in the current elderly population is superior to the brachiocubiti fistula in terms of easy cannulation and maturation. Primary outcome is one year patency We will also...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON33941

Source
ToetsingOnline

Brief title
ELBA Trial

Condition

- Nephropathies
- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
renal insufficiency and hemodialysis access

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: fonds wetenschappelijk onderzoek van afdeling heelkunde Sint franscicus Gasthuis en Maasstadziekenhuis

Intervention

Keyword: Basilic transposition, Ellbow fistula, hemodialysis, vascular access

Outcome measures

Primary outcome

primary study parameters:

1. is there a difference in primary patency after one year?

Secondary outcome

Secundary study parameters:

1. is there a difference in thrombosis-free interval?

2. is there a difference in the amount of interventions needed?

3. Is there a difference in usability ?

a. duration untill first cannulation

b. total time of non-usability as a result of revision operations

c. easy cannulation

d. time of compression for hemostasis after cannulation

e. complications: infection, thrombosis, aneurysm, haematoma, steal, edema

4. effect of fistula on periferal circulation

Study description

Background summary

According to current international standards (NKF K/DOQI guidelines) a brachiocubiti arteriovenous fistula is second choice for creating hemodialysis access in patiënts with end stage renal disease (ESRD). The most frequently used ellbow fistula are the brachiocephalic fistula or the Gracz fistula in which the perforating vein is used. When using the perforating vein one cannot predict if the fistula will drain in the superficially located cephalic vein or in the deeper located basilic vein. Drainage in the deeper basilic vein could result in a fistula that is difficult or even impossible to cannulate. The basilic vein is often of good quality because of its deep location. Because of the deep location transposition to a superficial location is needed to garantee easy cannulation. We think that in the current elderly dialysis population it may be that instead of a brachiocubiti fistula a basilic vein transposition is a better option because of the higher chance of maturation and easyer cannulation. Even though it implicates a larger wound area and longer operating time.

Study objective

The main objective of this study is to show that the basilic vein transposition in the current elderly population is superior to the brachiocubiti fistula in terms of easy cannulation and maturation. Primary outcome is one year patency We will also look at the difference in complications and interventions.

Study design

A non-blinded randomized multicenter trial

Intervention

Creation of an arteriovenous fistula for hemodialysis

The intervention will either be Basilic vein transposition or creation of an ellbow arteriovenous fistula.

Study burden and risks

- follow up will be conform standard protocol after creation of an upperarm fistula. In addition patients are asked to registrate pain by means of an VAS painscore pre and postoperative (4 times in total).

- as the intervention will be either one of two standard procedures the risks

of participation will not be different from standard treatment. Because the BB AVF requires a more extensive woundbed there might be a higher level of pain in that group. This will be documented with the VAS painscore

Contacts

Public
Sint Franciscus Gasthuis

Kleiweg 500
3045 PM Rotterdam
NL
Scientific
Sint Franciscus Gasthuis

Kleiweg 500
3045 PM Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-end stage renal failure with need for chronic intermittent hemodialysis
-creation of a forerarm fistula is not feasible, or failure of a forearm graft or fistula.
-diameter of brachial artery, cephalic and basilic upper-arm vein of at least 3.0 mm

Exclusion criteria

-active locoregional or systemic infection
-ischemia of ipsilateral arm
-not being able to understand and/or give informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	215
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL23188.101.08