The PINCH Study: Supervised preoperative forearm exercise to increase blood vessel diameter in patients that require an arteriovenous access for hemodialysis

Published: 12-12-2016
Last updated: 19-03-2025

To investigate whether pre-operative supervised forearm exercise increases blood vessel size and success rates of AVF surgery in end stage renal disease patients.

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

Summary

ID

NL-OMON50205

Source
ToetsingOnline

Brief title
The PINCH study

Condition

- Nephropathies
- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
Blood vessel diameter, Blood vessel size

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Wetenschapsfonds MCH-Bronovo en wetenschappelijke vakverenigingen

Intervention

Keyword: Arteriovenous fistula (AVF), Forearm exercise, Non-maturation, Vascular access

Outcome measures

Primary outcome

Per-patient change in cephalic vein or radial artery diameter after six weeks

of forearm exercise, as assessed by duplex ultrasound at pre-specified

locations in the forearm.

Secondary outcome

- Change in operative plan i.e. when the initial plan of brachiocephalic

fistula creation is changed into radiocephalic fistula creation following six

weeks of forearm exercise. Minimal cephalic vein diameter at the wrist must be

2.0mm in order to proceed for a radiocephalic fistula.

- Cephalic vein diameter end flow six weeks after the operation, as assessed by

duplex ultrasound.

- Per-patient change of cephalic or basilic vein diameter from the operation

until six weeks postoperatively.

- If applicable, shunt flow 6 and 12 weeks postoperatively

Study description

Background summary

The number of patients on hemodialysis worldwide is increasing. In the Netherlands the incidence is 115:1 million. This means almost 2000 new dialysispatients per year. A well functioning arterio-venous fistel (AVF) is essential for succesfull dialysis en form vital importance for dialysis patients.
A major problem in creating a AVF for dialysis purposes is the percentage of non-maturation (30-50%). This means that he AVF does not reach an adequate flow and diameter within 6 weeks after surgery. In this case frequent re-interventions are necessary and it is often necessary to create a new AVF, or patients are dependant on a synthetic graft or use of central venous catheters, with all associated risks (infection, trombosis, short patency). All this results in delay in the dialysis traject en causes significant morbidity.
The prefered site for creating an AVF is the wrist (a radio-cephalic AVF) of the non dominant arm, because the risk of ischemic complications for the hand is smallest in this case. However, non-maturation is more frequent in radio-cephalic AVF, correlating with a smaller diameter of blood vessels at this location.
Small, non randomized studies suggest that performing postoperative forearm exercises have a positive influence on the blood vessel diameter en therefore promotes the process of maturation. Bases on these results, international guidelines advise standard postoperative exercises after AFV surgery.
The significance of performing pre-operative pinch exercises has never been investigated, while theoretically this would promote vessel diameter before surgery and might make the operation technically easier and potentially decreases the non maturation rate. Because it is known that the succes of exercise therapy is correlating with the intensity of supervision and standardisation of these exercises, an electronically (app-based) training schedule, combined with structural physiotherapy can be of great importance.

Study objective

To investigate whether pre-operative supervised forearm exercise increases blood vessel size and success rates of AVF surgery in end stage renal disease patients.

Study design

Single blind randomized controlled trial

Intervention

Participants will receive a daily program of structured forearm exercises for the arm that is planned for surgery. At home training program adherence is stimulated and monitored for efficacy and frequency by validated e-devices coupled to a handgrip trainer. Moreover, patients are expected to attend

focused physiotherapy group sessions once a week. After six weeks, an additional Duplex ultrasound examination will be executed to compare blood vessel diameters. After the operation, patients are followed up according to regular protocol. The control group does not undergo forearm exercise prior to AVF surgery, as is standard practice to date. During the study period, all participants will be asked to fill in the e-questionnaires about quality of life, burden of disease and (study) treatment, and forearm exercises apart from the study protocol.

Study burden and risks

The burden is mainly due to physical fatigue during exercise. Moreover, there are about 5 additional site visits for physiotherapy, as many as possible planned on days that patients already have appointments in the outpatient clinic for other reasons. There will be six e-questionnaire moments during the exercise program. The risk of damage to the patient, besides temporary fatigue is neligible.

Contacts

Public
Haaglanden Medisch Centrum

Lijnbaan 32 32
Den Haag 2512 VA
NL
Scientific
Haaglanden Medisch Centrum

Lijnbaan 32 32
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients who are scheduled for creation of an AVF for maintenance haemodialysis.
2. Male or female * 18 years old.
3. Patients are able and willing to give written informed consent.
4. Patients are able to attend once weekly physiotherapy classes.
5. Patients have a cephalic vein diameter equalling at least 1mm.

Exclusion criteria

1. Any concurrent illness, disability or clinically significant abnormality that may, as judged
by the investigator, affect the interpretation of clinical efficacy or safety data or prevent
the subject from safely completing the assessments required by the protocol.
2. Current participation in another interventional clinical trial
3. Previous AVF in the ipsilateral arm
4. Patients who are unlikely to adequately comply with the trial*s procedures (due for
instance to medical conditions likely to require an extended interruption or discontinuation, history of substance abuse or noncompliance).
5. Patients with absent cephalic vein in the ipsilateral arm.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-12-2017
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-04-2020
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

ID: 26121
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59337.098.16
OMON	NL-OMON26121