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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26121

Source
Nationaal Trial Register

Brief title
The PINCH Study

Health condition

hemodialysis acces, AVF, maturation failure, nonmaturation, exercise, vein diameter

hemodialyse, toegangschirurgie, AVF, maturatie falen, nonmaturatie, training, vene diameter

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Lijnbaan 32
2512VA Den Haag
Source(s) of monetary or material Support: initiator sponsored

Intervention

Outcome measures

Primary outcome

To investigate whether supervised, monitored forearm exercise increases blood vessel size at pre-specified locations in the forearm of target vessels for AVF surgery in ESRD patients.

Secondary outcome

To investigate whether supervised, monitored forearm exercise leads to a change in surgical AVF site, using pre-specified criteria for the surgical plans.

- To investigate whether supervised, monitored forearm exercise increases AVF maturation rate, with maturation being a diameter of 6mm and a flow of 600m1/min

- To investigate whether response to supervised, monitored forearm exercise on top of absolute diameter, predicts AVF maturation

Study description

Background summary

Background: Failure of maturation occurs in 30-50% of creation of AV fistulas for hemodialysis, with highest rates in distal radiocephalic fistulas. This can partially be attributed to initial small blood vessel size with limited blood flow capacity. Forearm exercise has shown potential as stimulus for increasing blood vessel size in patients with end-stage renal disease (ESRD) and may promote maturation of AVFs in the upper limb when applied postoperatively. However, it is presently unknown if forearm exercise increases blood vessel size pre-operatively, which may facilitate more distal AVF creation, and might raise success rates of AVF surgery. This study will investigate these issues.
Methods and results: The PINCH trial is an investigator-initiated, multi-centre, single-blinded randomized controlled trial with 1:1 randomization to perform supervised fore-arm exercises, or no exercise 6 weeks pre-operatively before creation of an AVF. 40 patients receiving an AVF will be included. The main study parameters/endpoints are blood vessel diameter (cephalic or basilic vein and radial and ulnar artery), AVF surgical plan (radiocephalic or brachiobasilic/-cephalic), and three-month (assisted) maturation rate. The burden of the performed fore-arm exercises will be evaluated using Quality of life (KDQOL-SF Dutch version 1.2) and exercise specific questionnaires. The PINCH trial will start in June 2017. Enrolment is expected to be completed after two years.

Conclusions: The PINCH study is the first trial to evaluate the effect of pre-operative, supervised forearm exercises on vein diameter and fistula maturation in hemodialysis patients

Study objective

pre-operative, supervised forearm exercises have a positive influence on vein diameter and therefore might improve fistula maturation in hemodialysis patients

Study design

finalisation handgrip trainer coupled e-device may 2017

first inclusion: june 2017

ending enrollment: 2019

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 traìner. 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.

Contacts

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Eligibility criteria

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 parlicipation 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)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50205
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6226

Register	ID
NTR-old	NTR6382
CCMO	NL59337.098.16
OMON	NL-OMON50205

Study results