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Effect of a postoperative exercise program on arteriovenous fistula maturation

Submission date
16/03/2015

Recruitment status
No longer recruiting

Registration date
29/03/2015

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An arteriovenous fistula (AVF) is a connection of an artery to a vein. It causes extra pressure and blood flow into the vein, making it grow larger and providing easy access to blood vessels. It is still the method of choice for achieving vascular access (i.e. a surgically created vein used to remove blood from, and return blood to, the body) during dialysis for patients with advanced kidney failure, as it causes fewer complications (such as infections, thrombosis and even death) than other methods. However, central venous catheters (where a catheter is placed in a large vein in the neck, chest or groin) is still widely used, probably due to a delay in creating the AVF and problems with the maturation process (the time between the AVF is created and when it can used, which usually is about 1 month). It is therefore crucial to increase the maturation and use of AVF. Exercises in the pre- and postoperative period have been recommended by current vascular access guidelines as helpful to improve vascular access maturation, increasing flow and muscle mass, decreasing superficial fat, and enhancing vein prominence (size). Currently, preoperative exercise can increase the diameter of a vein and this is linked to an increase in AVF maturation. However, postoperative exercise programs (after AVF creation) have not been clearly shown to be useful. Only one study has looked at the effect of exercise after AVF creation and this had severe limitations (few patients, excessive early examinations and very low maturation rates). The aim of this study is to determine whether a postoperative exercise program can really increase AVF maturation at 1 month, and determine if exercises after AVF creation should or should not be recommended.

Who can participate?
Patients of all ages with advanced chronic kidney disease needing dialysis and candidates for a AVF.

What does the study involve?
After each patient have had AVF surgery, they are randomly allocated into one of two groups. Those in group 1 (exercise group) are asked to follow a specific exercise programme. Those in group 2 (control group) are asked not to perform specific exercises and follow their usual lifestyle. We then investigate AVF maturation for all patients in both groups after 1 month via physical examination and ultrasound.

What are the possible benefits and risks of participating?
There are no benefits or risks associated to taking part to our study, more than the possible (and investigated) benefit related to exercise itself.

Where is the study run from?
Hospital Clinic of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
November 2012 to November 2014

Who is funding the study?
Hospital Clinic of Barcelona (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Hospital Clinic Investigational Committee registration: 2013/8042 (Hospital Clinic, Barcelona, Spain)

Study information

Scientific Title
Effect of a postoperative exercise program on arteriovenous fistula maturation: a randomized controlled trial

Study objectives
A postoperative exercise program increase arteriovenous fistula maturation after its surgical creation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Clinic CEIC (Ethical Committee of Clinical Investigation) and Investigational Committee, 10/01/2013, ref: 2013/8042

Study design
A single-center randomized controlled trial (interventional) was designed, including all patients visited in our center, who were candidates to arteriovenous fistula creation. After this surgery, patients were randomized to exercise group (following a controlled postoperative exercise programÇ) or to control group (following usual life-style)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Arteriovenous fistula is a surgically connection between an artery and a vein, that is created as a method for achieving vascular access in chronic hemodialysis patients.

Interventions
After arteriovenous fistula creation, all patients will be randomized to an exercise or control group. Patients in the exercise group will be asked to follow a previously designed controlled exercise program (the exercises included a specific table with a flex-band for 1-month after AVF creation) and the control group will be asked not to perform specific exercises (following a usual lifestyle). Single-blind masking will be performed (specialists dedicated to this study will be blind to the results of randomization in all phases of the study; only the nurse instructing patients to follow the exercise program and the patients themselves will know the results of randomization).

Intervention Type
Behavioural

Primary outcome measure
Primary outcome is arteriovenous fistula maturation one month after fistula creation (yes/no, and % of arteriovenous fistula). It is measured by clinical and ultrasonographic methods:
1. Clinical maturation is defined, after physical examination by a dedicated nurse and medical specialists, as an easily palpable vein, with a straight-superficial segment, length more than 10 cm, sufficient diameter and good palpable thrill.
2. Ultrasonographic maturation is defined, after ultrasound examination, as a draining vein diameter ≥ 5 mm, skin-vein distance ≤ 6 mm and brachial blood flow rate (BFR) ≥ 500 mL/min.

Secondary outcome measures
N/A

Overall study start date
01/11/2012

Completion date
30/11/2014

Eligibility

Key inclusion criteria
All patients with chronic kidney diseases stages 5 (pre-dialysis) and 5D (hemodialysis) who visited in our center and are candidates for the creation of native AVF (arteriovenous fistula) in the upper extremity are invited to participate in this study. The inclusion criteria consisted of:
1. Ambulatory status
2. The ability to understand and perform the exercise program and attend a follow-up visit
3. Acceptance to participate
4. Provision of signed informed consent after receiving full information on the program

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
82 patients (41 per group) will be needed.

Key exclusion criteria
1. Patients with previous dysfunctioning AVF in the same arm (AVF repairs)
2. Prosthetic accesses
3. Known arterial or venous diseases in the same arm

Date of first enrolment

01/06/2013

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clinic
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Sponsor information

Organisation
Hospital Clinic

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Sponsor type
Hospital/treatment centre

Website
www.hospitalclinic.org

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Clinic, Barcelona, Spain

Results and Publications

Publication and dissemination plan
We will publish our results of the complete study, once finished.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016	22/01/2019	Yes	No