

# Effect of a postoperative exercise program on arteriovenous fistula maturation

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<b>Registration date</b> 29/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> 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 be 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 an AVF.

### What does the study involve?

After each patient has 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?

Dr Nestor Fontsero

FONTSERE@clinic.ub.es

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Nestor Fontsero

**ORCID ID**

<https://orcid.org/0000-0001-9598-9277>

**Contact details**

Hospital Clinic

C\Villarroel 170

Barcelona

Spain

08036

932275400

FONTSERE@clinic.ub.es

## Additional identifiers

**Protocol serial number**

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 program) or to control group (following usual life-style)

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

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  $\geq 5$  mm, skin-vein distance  $\leq 6$  mm and brachial blood flow rate (BFR)  $\geq 500$  mL/min.

### **Key secondary outcome(s)**

N/A

**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

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**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

C\ Villarroel, 170

Barcelona

Spain

08036

# Sponsor information

## Organisation

Hospital Clinic

## ROR

<https://ror.org/02a2kzf50>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Hospital Clinic, Barcelona, Spain

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/04/2016	22/01/2019	Yes	No