

# Comparison of end-to-side vs side-to-side arteriovenous fistula formation in chronic renal failure patients

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<b>Registration date</b> 31/08/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/09/2019	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Haemodialysis is a procedure that involves diverting blood to a machine to remove waste products and excess fluid. It is used when the kidneys stop working properly. Before haemodialysis can start, patients need to have a special blood vessel created in their arm by connecting an artery to a vein, called an autogenous arteriovenous fistula (AVF). The connection (anastomosis) between the artery and the vein can be performed in a side-to-side or end-to-side fashion. There is a lack of evidence to recommend one anastomosis type over the other. The aim of this study is to find out whether side-to-side AVF anastomosis is better than end-to-side anastomosis at 1 and 6 months follow-up.

### Who can participate?

Adult and senior patients (aged over 18) who need an elbow AVF for haemodialysis

### What does the study involve?

Every surgeon and centre participating in this study uses their preferred anastomosis type. Including the patient in the study requires close follow-up but no changes in treatment. The following information is collected:

1. Before the operation: participants' age, sex, other illnesses, previous arteriovenous accesses and central venous lines. A vein and artery ultrasound examination is also carried out.
2. At the time of the operation: the anastomosis type (side-to-side or end-to-side), the vein and artery used, time taken, any other procedures, vein blood flow
3. At 1 month and 6 months follow-up: complications, the status of the AVF, blood flow (ultrasound examination)

### What are the possible benefits and risks of participating?

Every surgeon and centre performs their preferred AVF anastomosis, and participating in this study does not change treatment. Participating in this study therefore does not carry any benefits or risks, other than the benefits and risks of AVF creation.

Where is the study run from?

1. Hospital Clínic, Universitat de Barcelona. Barcelona, Spain (lead centre)
2. Hospital Universitari Vall d'Hebron, Universitat Autònoma de Barcelona, Barcelona, Spain
3. Hospital de Mataró. Mataró, Barcelona, Spain
4. Hospital Universitari de Bellvitge, Universitat de Barcelona. l'Hospitalet, Barcelona, Spain
5. Parc de Salut - Hospital del Mar, Universitat Autònoma de Barcelona, Barcelona, Spain
6. Hospital Sant Joan de Déu - Fundació Althaia. Manresa, Barcelona, Spain

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

September 2016 to March 2018

Who is funding the study?

Hospital Clinic, University of Barcelona (Spain)

Who is the main contact?

Dr Gaspar Mestres

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

CEIC\_HCB\_2016\_0495

## Study information

### Scientific Title

Comparison of maturation and functionality of end-to-side vs side-to-side arteriovenous fistula formation as hemodialysis access in chronic renal failure patients

### Study objectives

As compared to end-to-side arteriovenous fistula (AVF) anastomosis, side-to-side anastomosis does not provide benefits in terms of maturation, functionality or complications at one and 6 months follow-up.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee and Investigation Committee, Hospital Clinic and University of Barcelona, 30/06/2016, ref: CEIC\_HCB\_2016\_0495

### **Primary study design**

Observational

### **Study design**

Prospective observational study, two arms

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

Treatment

### **Health condition(s) or problem(s) studied**

Patients that required the creation of an autogenous elbow arteriovenous fistula (AVF) as permanent access for chronic hemodialysis sessions

### **Interventions**

Every surgeon and center participating in this study will perform their preferred anastomosis type (side-to-side vs end-to-side), and including the patient in the study will require close follow-up but no changes in the therapeutic process.

Several data in the preoperative, intraoperative and postoperative period will be recorded:

1. Preoperative: age, sex, comorbidities (diabetes, hypertension, cardiopathy, pneumopathy), previous arteriovenous accesses, previous central venous catheters in the same side. Ultrasound exam (vein and artery patency and diameter)
2. Intraoperative: anastomosis type (side-to-side or end-to-side), vein and artery used, adjunctive procedures, venous outflow, operative time
3. One month follow-up: complications during follow-up, patency, maturation, utility of the AVF, flow (ultrasound)
4. 6 month follow-up: complications during follow-up, patency, maturation, utility of the AVF, flow (ultrasound)

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Maturation and utility of the AVF at one and 6 months follow-up:

1. Maturation will be defined, after physical examination by experienced and dedicated staff, as an easily palpable vein, with a straight-superficial segment, length more than 10 cm, sufficient diameter, and good palpable thrill (clinical maturation should assess an AVF that is expected to be suitable for hemodialysis [HD] access and considered appropriate for cannulation with two

needles and expected to deliver sufficient blood flow throughout the HD)

2. Functionality: an AVF that is currently being used, successfully, for HD access during HD sessions, delivering the prescribed blood flow without complications

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

Complications, secondary interventions and patency (primary, assisted primary and secondary patency) at one and 6 months follow-up.

1. Complications may include:

1.1. AVF thrombosis (occlusion and loss of patency of the AVF)

1.2. AVF-induced ischaemia VA stages 2 to 4 (extremity malperfusion after AVF creation, including stages 2 - loss of sensitivity, pain during HD or exercise, stages 3 - rest pain, stages 4 - digital tissue loss)

1.3. Venous hypertension syndrome: upper arm and hand edema, swelling, cyanosis or ulcers due to increase of venous pressure

2. Secondary interventions: any surgical or endovascular procedure performed over a previous AVF, in order to increase patency, avoid the occlusion of the AVF, to treat stenosis or other problems that may affect AVF utility, or procedures declotting a thrombosed AVF in order to restore patency and utility of this AVF

3. Patency (primary, assisted primary and secondary patency):

3.1. Primary patency: the interval between AVF creation and the first re-intervention (intervention-free access survival) for access dysfunction or thrombosis or the time of measurement of patency

3.2. Assisted primary patency: interval between AVF creation and the first occlusion (thrombosis-free access survival) or measurement of patency including operative/endovascular interventions to maintain the AVF

3.3. Secondary patency: interval between AVF creation and the abandonment of this AVF (i.e. thrombosis) after one or more interventions or achievement of a censored event (death, change of HD modality, loss for follow-up)

### **Completion date**

15/03/2018

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (more than 18 years of age)

2. Underwent new autogenous elbow arteriovenous fistulae as permanent vascular access for hemodialysis in the participating study centers

3. Primary accesses in this location (elbow)

4. In pre-dialysis or already under dialysis treatment

5. Understand this study

6. Able to come to control visits

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

133

**Key exclusion criteria**

1. Patients with previous native or prosthetic arteriovenous fistulae in the same elbow or proximally (previous distal wrist fistulas are allowed)
2. Previous history of ipsilateral deep vein thrombosis
3. Patients requiring prosthetic arteriovenous access
4. Patients that do not accept to participate in the study or refuse to come to control visits

**Date of first enrolment**

15/09/2016

**Date of final enrolment**

15/09/2017

**Locations****Countries of recruitment**

Spain

**Study participating centre**

**Hospital Clinic, Universitat de Barcelona**

C\ Villarroel 170

Barcelona

Spain

08036

**Study participating centre**

**Hospital Universitari Vall d'Hebron, Universitat Autònoma de Barcelona.**

Passeig de la Vall d'Hebron, 119-129

Barcelona

Spain

08035

**Study participating centre**

**Hospital de Mataró**

Carr. de Cirera, 230

Barcelona  
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08304

**Study participating centre**  
**Hospital Universitari de Bellvitge, Universitat de Barcelona**  
Feixa Llarga, s/n  
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**Study participating centre**  
**Parc de Salut Hospital del Mar**  
Passeig Marítim, 25-29  
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08003

**Study participating centre**  
**Hospital Sant Joan de Déu. Fundació Althaia**  
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## **Sponsor information**

**Organisation**  
Hospital Clinic, University of Barcelona

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

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

## Funder Name

Hospital Clinic, University of Barcelona

# 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	01/12/2019	05/09/2019	Yes	No