ISRCTN62033470 https://doi.org/10.1186/ISRCTN62033470

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

Submission date
23/08/2016

Recruitment status
No longer recruiting

Registration date
31/08/2016

Overall study status
Completed

Last Edited
05/09/2019

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
gasparmestres@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Gaspar Mestres

ORCID ID
http://orcid.org/0000-0002-8699-7037

Contact details
Hospital Clinic, University of Barcelona
C\Villarroel 170
Barcelona
Spain
08036
+34 (0)932 275 400
gasparmestres@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective observational study, two arms

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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)

Overall study start date
15/09/2016

Completion date
15/03/2018

Eligibility

Key inclusion criteria
1. Adult patients (more than 18 years of age)
2. Underwent new autogenous elbow arteriovenous fístulae 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

Age group
Mixed

Sex
Both

Target number of participants
330

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
Spain
08304

Study participating centre
Hospital Universitari de Bellvitge, Universitat de Barcelona
Feixa Llarga, s/n
Barcelona
Spain
08907

Study participating centre
Parc de Salut Hospital del Mar
Passeig Marítim, 25-29
Barcelona
Spain
08003

Study participating centre
Hospital Sant Joan de Déu. Fundació Althaia
C/ Dr. Joan Soler, s/n
Barcelona
Spain
08243

Sponsor information

Organisation
Hospital Clinic, University of Barcelona

Sponsor details
C\Villarroel 170
Barcelona
Spain
08036

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Clinic, University of Barcelona

Results and Publications

Publication and dissemination plan
Once finished our study, results will be published in a specialized peer-reviewed impact factor journal.

Intention to publish date
15/03/2019

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