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Can the use of a VasQ external support device improve the maturation and utilization of wrist distal arteriovenous fistulas?

Submission date
23/01/2023

Recruitment status
No longer recruiting

Registration date
26/01/2023

Overall study status
Completed

Last Edited
25/01/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
An arteriovenous fistula is a connection, made by a vascular surgeon, of an artery to a vein to provide access for hemodialysis, and distal (radiocephalic) fistulas (in the forearm) are considered the first option to offer in all patients who are candidates for hemodialysis. However, there is a high rate of early thrombosis (blood clots) and a lack of maturation after its creation, so new devices have been developed to improve these initial results. One of these devices is the VasQ external support (Laminate Medical, Israel), which improves the results in large accesses (proximal, humerocephalic or humerobasilic fistulas), but there are no randomized studies that demonstrate its usefulness in distal accesses (radiocephalic fistulas). The aim of this study is to find out whether the use of VasQ devices improves both clinical and ultrasound maturation of distal arteriovenous fistulas for hemodialysis.

Who can participate?
Patients aged 18 years or older who need a distal arteriovenous fistula (radiocephalic) for hemodialysis

What does the study involve?
Participating in the study may involve the usual preoperative visit and ultrasound image, and the conventional surgery or the implementation of the VasQ device, a device that has a CE mark and is being used in current practice, so both options are routine clinical practice. During follow-up, participants are asked to follow 1-year follow-up controls at 1, 3, 6 and 12 months, with clinical and ultrasound assessment of their accesses. This is the recommended follow-up in all vascular access guidelines (close follow-up of accesses with ultrasound and clinical assessment).

What are the possible benefits and risks of participating?
The benefit of participating in the study is that participants will be included in a close follow-up of the access, which is the recommended follow-up in all guidelines. Conventional fistulas and VasQ devices are performed following all standards of care, so no risks are expected due to

participation in the study. The VasQ device, in addition, seems to improve the maturation and patency (openness) of fistulae in the follow-up, so the researchers expect to improve conventional fistula results with this device.

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

When is the study starting and how long is it expected to run for?
January 2023 to February 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Gaspar Mestres, gmestres@clinic.cat

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
HCB/2022/1313

Study information

Scientific Title
Impact of VasQ external support device in maturation and utilization of radiocephalic arteriovenous fistulas: a randomized study

Study objectives
The use of VasQ devices improves both clinical and ultrasound maturation of distal arteriovenous fistulas for hemodialysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2023, Hospital Clinic of Barcelona, Medical Investigation Ethical Committee (Hospital Clinic, Barcelona, C\Villarroel 170, 08036, Barcelona, Spain; +34 (0)93 227 57 66; ceic@clinic.cat), ref: HCB/2022/1313

Primary study design
Interventional

Study design
Unicenter interventional single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Maturation and utilization of distal radial-cephalic arteriovenous fistulae for hemodialysis

Interventions
Patients with terminal renal insufficiency that have been proposed for a creation of a distal arteriovenous fistulae (radiocephalic) in the arm, will be randomized using simple randomization to the creation of a conventional distal fistula or with the placement of the VasQ device (external support intended to improve fistulae maturation and utilization). The maturation (primary objective), patency and usefulness of the accesses will be analyzed for 1 year after their creation, comparing both groups.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
VasQ externa support (Laminate Medical, Israel)

Primary outcome(s)
The percentage of maturation of radiocephalic arteriovenous fistulas after 1 year of its creation. A fistula is considered mature when is suitable to be punctured for hemodialysis sessions, after a specialized nurse or medical evaluation or ultrasound measurements, following the European Society for Vascular Surgery (ESVS) and Kidney Disease Outcomes Quality Initiative (KDOQUI) guideline definitions

Key secondary outcome(s)
1. Primary patency (PP), assisted primary patency (PA) and secondary patency (PS) at 1 year of follow-up
2. The use of these accesses in those patients in the hemodialysis program:
2.1. PP will be considered the patency of the vascular access until its first: open or endovascular procedure to avoid its occlusion; open or endovascular procedure to declot it; definitive

thrombosis or occlusion (time from creation to any procedure to prevent thrombosis, treat thrombosis, or definitive thrombosis)
2.2. Assisted PA will be considered the patency of the vascular access until its first: open or endovascular procedure to declot it; definitive thrombosis or occlusion (time from creation to any procedure to treat thrombosis, or definitive thrombosis)
2.3. PS will be considered the patency of the vascular access until its definitive thrombosis or definite (time from creation to definitive thrombosis)

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Patients with chronic renal failure stages 5 and 5D (renal failure in the pre-dialysis stage or in a hemodialysis program), candidates according to usual clinical practice for the creation of a radiocephalic (distal) arteriovenous fistula for hemodialysis
2. Adults (18 years or older), who understand the study and agree to participate in it
3. In the arm proposed for the creation of access (after evaluation of both and patient preference): distal cephalic vein after proximal tourniquet between 2 and 6 mm in diameter, patent, without significant stenosis, with continuity through the forearm and good connection with the deep venous system (by perforating elbow, cephalic or proximal basilic vein), less than 6 mm deep (ultrasound examination)
4. Radial artery of the same extremity, between 2 and 6 mm in diameter, with a distal triphasic curve (normal) and good radial pulse, without mural calcification or occlusion
5. Absence of ischemic or calciphylaxis lesions in the same limb
6. Absence of other arteriovenous accesses in the same upper extremity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients who do not agree to participate in the study
2. Patients who cannot or do not want to attend control visits
3. Allergy to Nitinol
4. Known presence of central venous stenosis or occlusion (axillary, subclavian veins, innominate trunk, or superior vena cava). In case of high suspicion, a preoperative phlebographic study will be carried out to rule it out, considering high suspicion or risk:

or central venous catheter holder for more than one year, or edema of the upper extremities with the previous creation of arteriovenous fistulas in the upper extremities, or abundant prepectoral collateral circulation, or pacemaker carrier on the same axis,
or surgery of the upper extremity or history of peripherally inserted central catheters
5. PICC- in the same extremity
6. Less than one year of life expectancy
7. Stenosis >50% in the target veins to be cannulated
8. Previous arteriovenous surgeries in that area or proximal in the same limb.
9. Cardiological criteria for the exclusion of arteriovenous fistulas (heart disease with low ventricular ejection fraction FEV <30%, severe pulmonary hypertension with PAP >50 mmHg, distal vasculopathy or unstable ischemic heart disease)
10. Not be a candidate for the creation of distal arteriovenous fistulas (radiocephalic):
10.1. Distal cephalic vein (forearm) or radial artery less than 2 mm in diameter
10.2. Vein without continuity (presence of stenosis or areas less than 2 mm in diameter) or without communication with proximal, superficial or deep veins

Date of first enrolment
15/02/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clinic Barcelona
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Sponsor information

Organisation
Hospital Clínic de Barcelona

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Gaspar Mestres. (gmestres@clinic.cat). Upon request, the researchers can share the final results data, and if required for metaanalysis, more detailed data referring to lost on follow-up, patencies and maturation. Data will not be shared until the end of follow-up, February 2025. As usual, all data will be submitted to a pseudonymization, to avoid identification of patients' characteristics.

IPD sharing plan summary
Available on request