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To determine whether repair of asymptomatic stenosis in arteriovenous fistula for hemodialysis can improve vascular access survival

Submission date
14/01/2013

Recruitment status
No longer recruiting

Registration date
31/01/2013

Overall study status
Completed

Last Edited
30/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Haemodialysis is a form of treatment that filters your blood to rid your body of harmful waste, extra salt, and water. It involves surgically connecting an artery to a vein to transfer your blood into the dialysis machine and back again. This modified blood vessel is called a fistula. Fistulas are at risk of developing stenosis, an abnormal narrowing of the blood vessel that leads to a reduction of the blood flow through the fistula. This may reduce its ability to function and may also lead to the formation of a blood clot inside the fistula that will completely block the blood flow through the vessel (thrombosis). In this case, the doctors will try to remove the clot and restore the blood flow inside the fistula (thrombectomy). Unfortunately, the thrombectomy is not always successful and the fistula has to be abandoned in some cases. For these reasons, doctors have developed guidelines that recommend to identify and correct stenosis when the fistula is not functioning well or when the blood flow is low, because correcting the stenosis reduces the risk of thrombosis and prolongs the life of the fistula. Stenosis, however, can be present in a fistula that is well functioning and has a high blood flow (called an asymptomatic stenosis), but we do not know whether the correction of this stenosis helps the patient by reducing the risk of complications. We performed a study to determine if treating an asymptomatic stenosis reduces the risk of thrombosis and prolongs the life of the fistula, compared with treating the stenosis only when the fistula is not functioning well or has a low flow, as suggested by the guidelines.

Who can participate?
Hemodialysis patients aged over 18 with a stenosis in a well-functioning fistula with a high blood flow.

What does the study involve?
The participants will be randomly divided into two groups. One group (the control group) will have the stenosis treated only when the fistula does not function well or when its blood flow is low, as suggested by the guidelines. The other group (the treatment group) will have the

stenosis corrected immediately , as soon the patient is included in the study. For all participants the doctor will decide how to treat the stenosis, choosing between two options that have the same chance of success (stenosis is corrected successfully and blood flow through the access increases in more than 95% of the cases). You may have a thin tube (catheter) with a small balloon at the end inserted into the fistula; when the tube is inside the stenosis, the balloon will be inflated to widen the stenosis (angioplasty). Alternatively, you may have an operation in which the stenosis will be treated by the surgeon by creating a new connection between the artery and the vein (neoanastomosis) or by replacing the narrow part of the fistula with a short synthetic tube (vascular graft). During the study, the function of your fistula will be evaluated by the nurses at every dialysis and the blood flow of the fistula measured every 3 to 4 months, to detect any problems that require treatment. If your fistula has a thrombosis, you will need an operation in which the doctors will attempt to remove the clot (thrombectomy). Unfortunately the thrombectomy is not always successful and if your fistula has to be abandoned, the doctors will create a new vascular access (a new fistula or place a vascular graft into your arm). In this case the doctors will place a tube into a large vein of your neck so you can continue to have dialysis while waiting for the new access.

What are the possible benefits and risks of participating?
If you are allocated to the control group, your stenosis will be treated as suggested by the guidelines and you will have a low risk of thrombosis and fistula loss. If you are allocated to the treatment group you will have the same risks of thrombosis and fistula loss of the control group, but you may need more interventions (angioplasty or surgical operation); on the other hand, you may have the benefit of having a lower chance of thrombosis and the fistula may have a longer life.

Where is the study run from?
The study is conducted at the Hemodialysis Unit at Policlicinico Borgo Roma of the Division of Nephrology and Dialysis of the Azienda Ospedaliera Universiataria Integrata Verona in Verona, Italy.

When is the study starting and how long is it expected to run for?
The study starts in October 2006 and will last until September 2013, recruiting patients for a period of 3 years.

Who is funding the study?
The study has no special funding, because all the procedures performed during the study (to detect and treat stenosis, thrombectomy, placement of a catheter for dialysis and a new vascular access) are part of the routine care of the hemodialysis patients, and these expenses are covered by the Italian National Health System (Servizio Sanitario Nazionale).

Who is the main contact?
Nicola Tessitore
nicola.tessitore@ospedaleuniverona.it

Contact information

Type(s)
Scientific

Contact name
Dr Nicola Tessitore

Contact details
Piazzale LA Scuro 10
Verona
Italy
37133
+39 0458124652
nicola.tessitore@ospedaleuniverona.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
To determine whether repair of asymptomatic stenosis in arteriovenous fistula for hemodialysis can improve vascular access survival: an open randomized comparative interventional trial

Study objectives
We tested the hypothesis of whether elective repair of subclinical stenosis (i.e. in a well-functioning access capable of delivering adequate dialysis dose) in arteriovenous fistula (AVFs) with a Qa>500 ml/min could decrease the risk of access failure (the composite of thrombosis and signs of impending thrombosis), improve access use-life, and be cost-effective by comparison with correcting stenosis only when it becomes hemodynamically significant due to the onset of dysfunction detected during dialysis, an otherwise explained decrease in the dose of dialysis delivered), or a Qa <400-500 ml/min, as recommended by the K/DOQI guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Trials, University Hospital Integrated Verona [Comitato Etico per la Sperimentazione Clinica, Azienda Ospedaliera Universitaria Integrata Verona], 26/09/2006, ref: Prog. Number 1131

Study design
Single-centre open randomized comparative interventional trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Asymptomatic AVF stenosis

Interventions
In the control group, stenosis will be corrected in response to access dysfunction or a Qa<400 ml /min.

In the treatment group, stenosis will be corrected electively within 2 weeks of enrolment, and imaging for restenosis (by angiography of duplex ultrasound) and re-stenosis repair during the follow-up are performed in cases of Qa<750 ml/min or a >25% drop in Qa. These Qa criteria were choosen because of their high sensitivity to detect stenosis in AVF in our experience (Tessitore et al., AJKD 2003, 42:331).

In both groups, stenosis will be repaired electively by percutaneous transluminal angioplasty (PTA) or surgery (a more proximal neoanastomosis or a PTFE interposition graft): the choice of intervention was made case by case at the discretion of and depending on the availability of the radiologist and the vascular surgeon with the view to correcting stenosis without any major reduction in the venous capital available for puncture (Tessitore et al., CJASN 2006; 1:448).

In both groups, thrombectomy was performed depending on the availability of the attending radiologist and vascular surgeon by manual catheter-directed thrombo-aspiration or surgical revision, with the aim of declotting thrombosed AVF within 48 hours of its detection.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Access failure, the composite of thrombosis or pre-emptive intervention triggered by signs of impending thrombosis (a Qa<300 ml/min, access recirculation, or a >60 ml/min drop of the prescribed Qb) (Tessitore et al., AJKD 2003, 42:331)
2. Access abandonment, because patency could not be restored after a thrombotic episode (because the access was considered unsalvageable or thrombectomy was unsuccessful), or a patent access was unsuitable for cannulation or unable to sustain adequate dialysis (i.e. a spKt /V<1.0 within a 4-hour hemodialysis session)

Secondary outcome measures

Direct cost of access treatment, including all expenses for surveillance and imaging during the follow-up, elective endovascular and surgical intervention, thrombectomy, placement of a new access or a cuffed and uncuffed temporary central venous catheter, and hospitalization.

Overall study start date
01/10/2006

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Age >18 years old, either sex
2. Hemodialysis patients with arteriovenous mature AVF with angiographically-proven significant (>50% reduction in vessel diameter) asymptomatic stenosis (i.e. in a well-functioning access capable of delivering a spKt/V >1.2 within a 4-hour period and no dialysis-related abnormalities) and a Qa >500 ml/min.
3. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 subjects, equally distributed between the control and treatment arms

Key exclusion criteria
Any endovascular or surgical intervention in the 3 months prior to enrolment

Date of first enrolment
01/10/2006

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Italy

Study participating centre
Piazzale LA Scuro 10
Verona
Italy
37133

Sponsor information

Organisation
Division of Pediatric Nephrology and Dialysis Unit (UOC Nefrologia e Dialisi dU) (Italy)

Sponsor details
Piazzale Stefani 1
Verona
Italy
37126
+39 045 8122528
direzionenefrovr@virgilio.it

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00sm8k518

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Division of Nephrology and Dialysis Azienda Ospedaliera Universitaria Integrata Verona (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014	30/01/2019	Yes	No