ISRCTN12288675 https://doi.org/10.1186/ISRCTN12288675

Does surgically closing a branch of the cephalic vein in the arm affect the openness of an arteriovenous fistula (a connection between an artery and a vein created to allow access to a kidney dialysis machine) in the forearm?

Submission date
23/09/2019

Recruitment status
No longer recruiting

Registration date
26/09/2019

Overall study status
Completed

Last Edited
01/05/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
When people need regular hemodialysis (filtering waste and unneeded water from the blood by pumping the blood through a machine and then passing it back into the patient) because their kidneys have failed, they need to have a site of easy access to the blood created. An arteriovenous fistula (AVF) is where a vein and an artery, usually in the forearm, are connected together surgically. This creates higher blood flow in this section of vein, which stimulates the vein to grow stronger walls and a larger opening. The AVF allows the vein to be regularly punctured in two places to allow blood to be pumped out to the dialysis machine and back into the arm from the machine without damaging the vein.
It is thought that ligating (tying closed) a part of the cephalic vein (one of the blood vessels that carries blood from the hand back towards the heart) might help the AVF stay open and strong. This study aims to investigate this by comparing AVFs created with and without ligating part of the cephalic vein.

Who can participate?
Adults who need an AVF to enable regular hemodialysis.

What does the study involve?
Participants will be randomly allocated into two groups. Both will have an AVF created as usual, except that one group will also have the dorsal branch of the cephalic vein ligated.

What are the possible benefits and risks of participating?
In general, there is not any harmful effects for all participants of the two groups.

Where is the study run from?
The People's Hospital of Zhengzhou University (China)

When is the study starting and how long is it expected to run for?
January 2013 to February 2016

Who is funding the study?
The Key Science and Technology Program of Henan Province (China)

Who is the main contact?
Mrs Lu Yang, 1277341892@qq.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
15043

Study information

Scientific Title
Does ligation of the dorsal branch of the cephalic vein affect the patency of a distal forearm arteriovenous fistula of maintenance hemodialysis patients? A randomised study

Study objectives

We aimed to compare the patency of the radiocephalic arteriovenous fistula (RCAVF) in patients with and without ligation of the dorsal branch of the cephalic vein.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2014, Ethics Committee of Zhengzhou University People's Hospital (Huanghe Rd/Jinger Rd, Zhengzhou, China, +86 87160680; hnsrmyykyll@163.com), ref: 15043

Study design
Single-centre randomised controlled 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 a contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Arteriovenous fistula created with and without ligation of the dorsal branch of the cephalic vein

Interventions
All patients included in were randomly divided into two groups, the group with ligation of the dorsal branch of the cephalic vein and the group without ligation of the dorsal branch of the cephalic vein, by sealed-envelope randomization. All patients underwent arteriovenous fistula (AVF) surgery, with the dorsal branch ligated or unligated. Participants were followed up and the AVF assessed at 90, 180, and 360 days after the surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Primary patency rate of the AVF, defined as the time from the establishment of the fistula to initial percutaneous transluminal angioplasty (PTA) or application of another intervention method to maintain the fistula patency

Secondary outcome measures
1. Secondary patency rate of the AVF, defined as the time from fistula establishment to fistula abandonment, or thrombosis needing a re-establishment of a new fistula

2. Blood flow of the AVF recorded by the hemodialysis machine at 90, 180, and 360 days after the surgery
3. Venous pressure of the AVF recorded by the hemodialysis machine at 90, 180, and 360 days after the surgery
4. AVF diameter assessed by duplex ultrasound using a color Doppler ultrasound machine at 90, 180, and 360 days after the surgery
5. AVF blood-flow volume assessed by duplex ultrasound using a color Doppler ultrasound machine at 90, 180, and 360 days after the surgery
6. Physical examination of AVF condition, with palpation, auscultation and identification of AVF thrill, at 90, 180, and 360 days after the surgery.

Overall study start date
01/01/2013

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Cephalic vein dorsal branch, confirmed via vein mapping before the procedure
2. Surgical procedure assessed as feasible by experienced surgeons via clinical assessment of the arterial pulse, expansion of the vein after blocking the proximal blood flow with a tourniquet, and bilateral arm blood pressure. Moreover, bilateral vascular assessment, including vascular diameters and arterial blood flow, was performed by duplex ultrasound.
3. Adequate arterial blood flow to the hand, confirmed by negative findings obtained on Allen’s test preoperatively

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
58

Total final enrolment
115

Key exclusion criteria
1. Patients without a cephalic vein dorsal branch
2. Patients who were unable to provide informed consent

Date of first enrolment
01/02/2014

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
China

Study participating centre
The People’s Hospital of Zhengzhou University
No. 7 Weiwu Road
Zhengzhou
China
450003

Sponsor information

Organisation
The People’s Hospital of Zhengzhou University

Sponsor details
No.7 Weiwu Rd
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(0371)65580070
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Sponsor type
Hospital/treatment centre

Website
http://www.hnsrmyy.net/

ROR
https://ror.org/04tgrpw60

Funder(s)

Funder type
Government

Funder Name
Science and Technology Department of Henan Province

Alternative Name(s)
, Department of Science and Technology, Henan Province, Henan Provincial Science and Technology Department, Henan Provincial Department of Science and Technology

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a journal.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/04/2020	01/05/2020	Yes	No