

# 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?

<b>Submission date</b> 23/09/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/05/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

**Contact name**  
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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; hnsrmykyll@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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**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?
<a href="#">Results article</a>	results	29/04/2020	01/05/2020	Yes	No