

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of the arm basilic vein transposition in brachio basilic arteriovenous fistulas dialysability in chronic renal failure

#### Protocol summary

##### Summary

Those hemodialysis candidate patients with a brachio basilic arteriovenous fistula because of the lack of suitable cephalic vein are included in this study after they meet the inclusion criteria. They will be undergone a basilic vein transposition surgery. In this operation, the basilic vein is totally released from beneath the deep fascia and proximity of the brachial artery and median nerve and transferred to the superficial subcutaneous space and lateralized at least 4 centimeter and fixed in this area. Follow-up is done in days 1,7,14 and 45 after the surgery for detecting the complications. Doppler flowmetry and evaluation for dialysability is done at day 45. The operation will be evaluated as "successful" if the vein could be cannulated by two access line and the patient could be dialysed for at least 4 hours with a 250 ml per minute flow for at leasts 3 sessions.

#### General information

##### Acronym

Basilic vein transposition in brachio basilic arteriovenous fistulas

##### IRCT registration information

IRCT registration number: **IRCT2014110716473N3**

Registration date: **2014-11-09, 1393/08/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-09, 1393/08/18

##### Registrant information

###### Name

Farzad Kakaei

###### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 1317

##### Email address

fkakaei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research vice-chancellor of Tabriz University of medical sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of the arm basilic vein transposition in brachio basilic arteriovenous fistulas dialysability in chronic renal failure

##### Public title

Evaluation of the effect of the arm basilic vein transposition in brachio basilic arteriovenous fistulas dialysability in chronic renal failure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Brachio basilic arteriovenous fistula for hemodialysis; minimum venous flow of 400 ml per minute; minimum venous diameter of 6 mm; no arterial steal syndrome; no venous hypertension; no significant skin lesion in the arm region; at least 2 months interval after the surgery; failure to access by the most

experienced dialysis nurse at least for 3 times. Exclusion criteria: venous flow less than 400 ml per minute; venous diameter less than 6 mm; fibrous changes of proximal basilic vein; less than 10 cm of releasable vein because of every reason; venous hypertension; steal syndrome; deformity of the arm; significant chronic or infectious skin lesion in the arm region; death in the follow-up period before the first dialysis attempt

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 30

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Tabriz University of medical sciences

###### **Street address**

Golgasht St.

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2014-02-24, 1392/12/05

##### **Ethics committee reference number**

5/4/10754

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Chronic kidney disease

##### **ICD-10 code**

N18.5

##### **ICD-10 code description**

Chronic kidney disease, stage 5

### **Primary outcomes**

#### **1**

##### **Description**

dialysability

##### **Timepoint**

45 days after the surgery

##### **Method of measurement**

By the dialysis nurse

#### **2**

##### **Description**

basilic vein blood flow difference

##### **Timepoint**

before and 45 days after the surgery

##### **Method of measurement**

by doppler sonography

#### **3**

##### **Description**

basilic vein diameter difference

##### **Timepoint**

before and 45 days after the surgery

##### **Method of measurement**

by doppler sonography

#### **4**

##### **Description**

length of releasable basilic vein

##### **Timepoint**

intraoperative finding

##### **Method of measurement**

by a ruler in centimeter

#### **5**

##### **Description**

maximum distance of basilic vein thrill from the skin incision

##### **Timepoint**

45 days after the surgery

##### **Method of measurement**

by a ruler in centimeter

### **Secondary outcomes**

#### **1**

##### **Description**

patient's age

##### **Timepoint**

before the operation

##### **Method of measurement**

in years

#### **2**

##### **Description**

patient's gender

**Timepoint**

before the operation

**Method of measurement**

male or female

**3****Description**

cause of renal failure

**Timepoint**

before the operation

**Method of measurement**

by questionnaire

**4****Description**

duration of the disease

**Timepoint**

before the operation

**Method of measurement**

by questionnaire in months

**5****Description**

circumference of the midforearm

**Timepoint**

before and 45 days after the operation

**Method of measurement**

with a tape in centimeter

**6****Description**

arterial steal syndrome

**Timepoint**

45 days after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**7****Description**

venous hypertension

**Timepoint**

45 days after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**8****Description**

bleeding

**Timepoint**

24 hours after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**9****Description**

hematoma

**Timepoint**

24 hours after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**10****Description**

wound infection

**Timepoint**

1,7,14 days after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**11****Description**

nerve injury

**Timepoint**

1,7,14 days after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**12****Description**

distal neuropathy

**Timepoint**

1,7,14 days after the operation

**Method of measurement**

by the surgeon according to history and physical exam

**Intervention groups****1****Description**

transposition (superficialization and lateralization) of arm basilic vein

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Ahad Hasankhani

**Street address**

Surgery Ward

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research vice-chancellor of Tabriz University of

medical sciences

**Full name of responsible person**

Mohammad Reza Rashidi

**Street address**

Golgasht St.

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research vice-chancellor of Tabriz University of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of medical sciences

**Full name of responsible person**

Farzad Kakaei

**Position**

Associate professor of general and vascular surgery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*