

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

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Name of organization / entity

Tabriz University of Medical Sciences

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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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Web page address

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