

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of vascular patency in basilic vein transposition compared to straight 6-mm grafts, as upper arm vascular access, in hemodialysis patients.

Protocol summary

Summary

The aim of performing this study is to investigate the patency of basilic vein transposition with 6 mm prosthetic brachioaxillary access grafts in hemodialysis patients. The study is designed as multicenter randomized double blind clinical trial. Sixty hemodialysis patients who met the inclusion criteria including no possibility of embedding the radiocephalic or brachiocephalic arteriovenous fistula or already created fistula but has been complicated and not to be usable, are divided randomly in one of the two groups (n=30) including basilic vein transposition or brachioaxillary prosthetic 6 mm arteriovenous graft operation group. Then the patency of created dialysis access as primary outcome and their related complications as secondary outcome will evaluated in two studied groups for at least one year follow up of the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070726023N1**

Registration date: **2016-10-13, 1395/07/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-13, 1395/07/22

Registrant information

Name

Pouya Tayebi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5311

Email address

tayebip941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2017-07-10, 1396/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vascular patency in basilic vein transposition compared to straight 6-mm grafts, as upper arm vascular access, in hemodialysis patients.

Public title

Patency comparison between two different kind of vascular accesses in hemodialysis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients Suffering end stage renal diseases with no possibility of creating the radiocephalic or brachiocephalic arteriovenous fistula for hemodialysis or they already have fistula but it has been damaged and unusable; No previous Basilic vein transposition or arteriovenous graft in the site of operation; No history of

current medication with anticoagulants or antiplatelet agents; Age 30-80 years old. Exclusion criteria: Anticoagulant or antiplatelet treatment after surgery and during follows up; cease hemodialysis from the created access after the operation for any reason.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random numbers table was used for the randomization in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical sciences, Daneshgah street

City

Mashhad

Postal code

9177899191

Approval date

2016-08-17, 1395/05/27

Ethics committee reference number

IR.MUMS.fm.REC.1395.91

Health conditions studied

1

Description of health condition studied

Chronic Renal Failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Access patency time

Timepoint

2 weeks, 1, 2, 3, 6 months then every 3 months after surgery up to one year

Method of measurement

Observation for finding the evidence of created access obstruction or successful dialysis

Secondary outcomes

1

Description

Presence of a palpable thrill in created access

Timepoint

2 weeks, 1, 2, 3, 6 months then every 3 months after surgery up to one year

Method of measurement

Dialysis Access physical examination for thrill strength and consistency

Intervention groups

1

Description

Intervention group 1: in order to creating dialysis vascular access, surgical operation will be done to perform basilic vein transposition. In this group after explore and superficialisation of the basilic vein, vascular anastomosis will be done with brachial artery.

Category

Treatment - Surgery

2

Description

Intervention group 2: Surgical operation for creating brachioaxillary prosthetic 6 mm graft between axillary vein and brachial artery. In this group after axillary vein and brachial artery exploration the graft passed from the anterior of arm and vascular anastomosis will be done for graft embedding.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Vascular surgery Department

Full name of responsible person

Dr Pouya Tayebi

Street address

Ebne sina Ave, Doctora crossroads

City

Mashhad

2**Recruitment center****Name of recruitment center**Imam Khomeini Hospital, Vascular Surgery
Department**Full name of responsible person**

Dr Mahdi Davoudi

Street address

Razi Ave

City

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research of Mashhad University of
Medical Sciences**Full name of responsible person**

Dr Mohsen Tafaghodi

Street addressVice chancellor of research, Ghoreishi building,
Daneshgah st.**City**

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research of Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Pouya Tayebi

Position

Fellowship of Vascular Surgery

Other areas of specialty/work**Street address**

Imam Reza Hospital, Vascular Surgery Department

City

Mashhad

Postal code**Phone**

+98 51 3841 2088

Fax**Email**

tayebip941@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Pouya Tayebi

Position

Fellowship of Vascular Surgery

Other areas of specialty/work**Street address**

Imam Reza Hospital, Vascular Surgery Department

City

Mashhad

Postal code

00985138412088

Phone

+98 51 3841 2088

Fax**Email**

tayebip941@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Pouya Tayebi

Position

Fellowship of Vascular Surgery

Other areas of specialty/work**Street address**

Imam Reza Hospital, Vascular Surgery Department

City

Mashhad

Postal code**Phone**

+98 51 3841 2088

Fax**Email**

tayebip941@mums.ac.ir

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