Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between the primary patency time of basilic vein transposition and prosthetic brachioaxillary access grafts in hemodialysis patients

Protocol summary

Summary

The objective of this randomized trial is to investigate the primary patency time of basilic vein transposition and prosthetic brachioaxillary access grafts in hemodialysis patients. In this study, 60 hemodialysis patients who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control group. The patients in two intervention groups will be operated for Basilic vein transpositions (BVT) or Arteriovenous bypass grafts (AVGs) and the duration of suitable performance of created hemodialysis access will be recorded as primary patency time and will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101175633N1**
Registration date: **2011-12-08, 1390/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-08, 1390/09/17

Registrant information

Name

Mahdi Davoudi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1225 6329

Email address

mdavoudi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research affairs of Mazandaran University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the primary patency time of basilic vein transposition and prosthetic brachioaxillary access grafts in hemodialysis patients

Public title

Comparison of the primary patency time in two diffrent kind of hemodialysis access in hemodialysis pateints

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: suffering from end stage renal disease that candidate for long time hemodialysis but there are no chance of radio or brachiocephalic arteriovenous fistula or failure of previously existed one, 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, no hemodialysis from the created access after the operation

Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences
Street address
Vice chancellor of research affairs, Moalem square
City
Sari
Postal code
Approval date
2011-04-20, 1390/01/31
Ethics committee reference number
89-178

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease
ICD-10 code
N18.0
ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Primary patency time of created dialysis access
Timepoint
2 weeks, 1, 2, 3, 6 months then every 3 months after surgery
Method of measurement
No evidence of access fail or unsuccessful dialysis from the created access

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
Method of measurement
a palpable thrill as well as the strength and consistency

Intervention groups

1

Description
Operation to create hemodialysis access for arteriovenous graft including exploration of Barachial artery and Axillary vein and pass the graft from subcutaneous area of arm and then vascular anastomosis in proximal side with Axillary vein and in distal side with Brachial artery.
Category
Treatment - Surgery

2

Description
Operation to create hemodialysis access for Basilicvein transposition; including Basilic vein transposition from depth of arm to subcutaneous area and vascular anastomose with brachial artery will be done.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Vascular Surgery Clinic at Emam Khomeini Hospital
Full name of responsible person
Dr Pouya Tayebi
Street address
Imam Khomeini Hospital - Sari
City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sacinces Vice Chancellor of Research
Full name of responsible person
Dr Ahmad Ali Enayati
Street address
Moalem Square, Mazandaran University of Medical Sacinces Vice Chancellor of Research affairs
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sacinces Vice Chancellor of Research
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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Pouya Tayebi
Position
Resident of General Surgery
Other areas of specialty/work
Street address
Department of General Surgery at Imam Khomeini Hospital - Sari
City
Sari
Postal code
Phone
+98 15 1225 6329
Fax
Email
p.tayebi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Pouya Tayebi
Position
Resident of General Surgery
Other areas of specialty/work
Street address
Department of General Surgery at Imam Khomeini Hospital - Sari
City
Sari
Postal code
Phone
+98 15 1225 6329
Fax
Email
p.tayebi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University Of Medical Sciences
Full name of responsible person
Dr Pouya Tayebi
Position
Resident of General Surgery
Other areas of specialty/work
Street address
Department of General Surgery at Imam Khomeini Hospital - Sari
City
Sari
Postal code
Phone
+98 15 1225 6329
Fax
Email
p.tayebi@yahoo.com
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