

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

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

Protocol summary

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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.

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

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

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 different kind of hemodialysis access in hemodialysis patients

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 Brachial 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 Sciences Vice
Chancellor of Research

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Moalem Square, Mazandaran University of Medical
Sciences 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 Sciences 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**

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Hospital - Sari

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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

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

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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