

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A comparison between the primary patency time of prosthetic arterio venous access graft(6mm) and prosthetic arterio venous access graft (4-7mm)in hemodialysis patients

Protocol summary

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Summary

The objective of this randomized trial is to investigate the primary patency time of two different types prosthetic brachioaxillary access grafts in hemodialysis patients. In this study, 30 hemodialysis patients who meet the inclusion /exclusion criteria will be recruited and randomly assigned in to intervention or control group. The patients in two intervention groups will be operated for arteriovenous bypass graft(6mm)or arteriovenous bypass graft (4-7mm)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 Mazandaran University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211045633N2**

Registration date: **2013-04-06, 1392/01/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-06, 1392/01/17

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 prosthetic arterio venous access graft(6mm) and prosthetic arterio venous access graft (4-7mm)in hemodialysis patients

Public title

A comparison the primary patency time between the two types of grafts in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:no history of previous AVG;do not use anticoagulant drugs exclusion criteria:previous AVG;using anticoagulant drugs

Age

From **30 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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,
Sari

City
Sari

Postal code

Approval date
2012-11-07, 1391/08/17

Ethics committee reference number
91-133

Health conditions studied

1

Description of health condition studied
progressive renal failure

ICD-10 code
N18.0

ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
primary patency time

Timepoint
2weeks, 1month, 2months, 3months, 6months, after
every 3months to years after surgeries

Method of measurement
doppler sonography, examination

Secondary outcomes

1

Description
symptoms of thrombosis(pain,redness,swelling)

Timepoint
2weeks,1month,2months,3months,6months,after every
3months to2 years after surgery

Method of measurement
examination,observation

2

Description
thrill in embedded pathway

Timepoint
2weeks,1month,2months,3months,6months,after every
3months to2 years after surgery

Method of measurement
examination,observation

3

Description
symptoms of infection(pain,redness,swelling)

Timepoint
2weeks,1month,2months,3months,6months,after every
3months to2 years after surgery

Method of measurement
examination,observation

Intervention groups

1

Description
Operation to create hemodialysis access for
arteriovenous graft including exploration of brachial
artery and axillary vein and pass the graft 6 mm 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
arteriovenous graft including exploration of brachial
artery and axillary vein and pass the graft(4-7mm) 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Vascular Surgery Clinic at Imam Khomeini Hospital

Full name of responsible person

Dr. Azadeh Beheshtian(Resident of General Surgery)

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

Mazandaran University of Medical Sciences Vice
Chancellor of Research affairs, Moalem square, Sari

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. Azadeh Beheshtian

Position

Resident of General Surgery

Other areas of specialty/work

Street address

Department of General surgery at Imam khomeini
Hospital-sari

City

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Postal code

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abeheshtian2000@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Azadeh Beheshtian

Position

Resident of General Surgery

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Azadeh Beheshtian

Position

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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