

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison study of the PTFE graft patency rate and the complications in the superficial and the common femoral arteries in the dialysis patients.

Protocol summary

Summary

The objectives: The aim of this study is to assess the efficacy and safety of a PTFE bridge graft between the superficial femoral artery and vein. The result is to compare with the conventional method- the graft placement between the common femoral artery and vein. The participants are those patients who failed to accomplish the conventional angioaccess procedures. main outcome measure (variable): The graft primary patency rate in the superficial femoral artery and result is to compare with the common femoral artery. The planning: This study is a blind randomized clinical trial set up among dialysis patients aged 28 to 86, admitted to the Imam Reza educational Hospital, Kermanshah University of Medical Sciences, who are candidates for the graft placement in the lower extremities. The main criteria for inclusion: Patients unable to receive the more conventional angioaccess procedures. The main criteria for exclusion: Patients with malignancy and coagulopathy. The intervention and methods: a total number of 40 patients are randomly divided into two groups; in the first group (intervention), with the graft being placed between the superficial femoral artery and vein. In the second group having undertaken the conventional method, the graft is placed between the common femoral artery and vein. The both groups are to be visited in the interval of a week and then every three months for up to a year, during which, the patency rate and the complications such as thrombosis, infection, hematoma and pseudoaneurism are to be assessed. The data from each group are to be studied and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021812514N1**

Registration date: **2013-05-12, 1392/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

Name

Hojat Bahramabadi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6312

Email address

dr.b.bahramabadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of the PTFE graft patency rate and

the complications in the superficial and the common femoral arteries in the dialysis patients.

Public title

A comparison between the two methods of artificial graft placement in the superficial and the common femoral arteries.

Purpose

Treatment

Inclusion/Exclusion criteria

The main criteria for inclusion: Patients in whom it is not possible more arteriovenous fistulas be accomplished

The main criteria for exclusion: Patients with malignancy and coagulopathy are excluded

Age

From **28 years** old to **86 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Postal code

6714415333

Approval date

2013-01-15, 1391/10/26

Ethics committee reference number

48647

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

Comparison of graft patency rate

Timepoint

Every three months

Method of measurement

Surgeon diagnosis

Secondary outcomes

1

Description

pseudoaneurysm

Timepoint

Every three months

Method of measurement

Surgeon diagnosis

2

Description

Graft thrombosis

Timepoint

Every three months

Method of measurement

Surgeon diagnosis

3

Description

Infection

Timepoint

Every three months

Method of measurement

Surgeon diagnosis

4

Description

Hematoma Hematom

Timepoint

Every three months

Method of measurement

Surgeon diagnosis

Intervention groups

1

Description

In the intervention group, the synthetic graft for access to dialysis is placed between the superficial femoral artery and vein.

Category

Treatment - Surgery

2

Description

In the control group using the conventional method, the synthetic graft for access to dialysis is placed between the common femoral artery and vein.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational Imam Reza Hospital, kermanshah university of medical sciences.

Full name of responsible person

Bahramabadi Hojat

Street address

The General Surgery Department, Imam Reza Hospital, Parastar Blvd, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences, Shid Behshti blvd, Kermans

Full name of responsible person

Najafi Farid

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Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences, Shid Behshti blvd, Kermans

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

Kermanshah University of Medical Sciences

Full name of responsible person

Bahramabadi Hojat

Position

Resident of general 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