

# 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

##### Street address

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

##### City

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

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Sadeghi Ezatollah

##### Position

Vascular Surgeon

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## Person responsible for updating data

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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*