

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparative study on the efficacy of flexion and non-flexin graft in dialysis patients during a six-month follow-up period

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Comparative study on the efficacy of flexion and non-flexin graft in dialysis patients during a six-month follow-up period

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

#### Registration date

2019-11-10, 1398/08/19

#### Design

The study is a clinical trial with parallel groups. Patients are those who need long-term dialysis. Fifty patients were selected by convenience sampling method and then randomly divided into two groups. Flexin and non-flexin grafts were included in this trial. Intervention groups are parallel and cannot be blinded.

#### Registrant information

##### Name

Mohammad Reza Sobhiyeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3427 6333

##### Email address

mohammadreza.sobhie@kums.ac.ir

#### Settings and conduct

Location: Kermanshah Imam Reza Hospital Dialysis Center Implementation: Evaluation of patients with postoperative hematoma by clinical examination Graft Function with Clinical Examination and Color Doppler Ultrasound Infection with clinical examination

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent and no previous history of intravenous arterial fistula. No history of central venous destruction. Exclusion criteria: non-cooperation for follow-up Immune-attenuating drug use Autoimmune Disease. Taking an anticoagulant drug. Antibiotic drug use

#### Expected recruitment start date

2019-11-20, 1398/08/29

#### Expected recruitment end date

2020-04-21, 1399/02/02

#### Intervention groups

The study is divided into two groups: Group 1: There are people who use flexin graft Group 2: There are people who use non-flexin graft

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Central venous destruction rate The fastest time to dialysis Graft stenosis Infection rate

#### Trial completion date

empty

#### General information

#### Scientific title

Comparative study on the efficacy of flexion and non-flexin graft in dialysis patients during a six-month follow-up period

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180223038837N3**

Registration date: **2019-11-10, 1398/08/19**

#### Public title

Comparative study on the efficacy of flexion and non-flexin graft in dialysis patients during a six-month follow-

up period

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Written and informed patient satisfaction No previous history of central venous destruction No previous history of graft for dialysis

### Exclusion criteria:

Failure to cooperate for follow-up Immune-attenuating drug use Autoimmune disease Taking anti-coagulants Taking antibiotics

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, a list of four random permutation blocks consisting of permutations of the letters B and A, for example AB and BA, was prepared by the statistical consultant using PAFF software. One person outside the selection researchers (operating room personnel) and qualified people are divided into groups

## 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

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Imam reza hospital, parstar Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

671441533

#### Approval date

2019-08-16, 1398/05/25

## Ethics committee reference number

IR.KUMS.REC.1398.532

## Health conditions studied

### 1

#### Description of health condition studied

Patients in need of dialysis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Stenosis after graft insertion

#### Timepoint

One month after graft placement, three months after graft placement, six months after graft placement

#### Method of measurement

Color Doppler Ultrasound

### 2

#### Description

pseudoaneurism

#### Timepoint

One month after graft placement, three months after graft placement, six months after graft placement

#### Method of measurement

Examination and ultrasound

## Secondary outcomes

### 1

#### Description

Central vein destruction

#### Timepoint

One month after graft placement, three months after graft placement, six months after graft placement

#### Method of measurement

Color Doppler Ultrasound

### 2

#### Description

infection rate

#### Timepoint

One month after graft placement, three months after graft placement, six months after graft placement

#### Method of measurement

examination

## Intervention groups

### 1

#### Description

Intervention group: In this group, the selected patients are transferred to the operating room. The procedure is determined on the arm and after washing the operation site, local anesthesia is injected into the ante cubital area and the axillary region and then the skin is cut. The subcutaneous is dissected and brachial and axillary vessels are exposed. Flexin graft is then anastomosis between brachial artery and axillary vein.

#### Category

Treatment - Devices

### 2

#### Description

Control group: In this group, the selected patients are transferred to the operating room. The procedure is determined on the arm and after washing the operation site, local anesthesia is injected into the ante cubital area and the axillary region and then the skin is cut. The subcutaneous is dissected and brachial and axillary vessels are exposed. The jotec graft is then anastomotic between the brachial artery and the axillary vein.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Mohammadreza sobhieh

##### Street address

parastar Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

671441533

##### Phone

+98 83 3427 6333

##### Email

mreza.sobhiyeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Farid Najafi

##### Street address

parstar blvd

##### City

kermanshah

##### Province

Kermanshah

##### Postal code

671441533

##### Phone

+98 83 3837 0541

##### Email

Farid\_n32@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Sobhiyeh

##### Position

Associate Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

General Surgery

##### Street address

Parstar Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

671441533

##### Phone

+98 912 183 7405

##### Email

Mreza.sobhiyeh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Sobhiyeh

##### Position

Associate Professor

##### Latest degree

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Parastar Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

671441533

**Phone**

+98 83 3427 6333

**Email**

Mreza.sobhiyeh@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Behzad Soleimani

**Position**

Resident of Surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Parstar Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

671441533

**Phone**

+98 83 3427 6333

**Email**

Drbehzad66@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

in the case of the participant's data file, three months after the publication of the article , and after unidentification of the person, the request can be send by email

**When the data will become available and for how long**

Three months after the article is published, it is possible to send it by email.

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Mention the author's name in the extracted article. In this case, any statistical analysis is permitted.

**From where data/document is obtainable**

By email with Dr. Mohammad Reza Sobhyeh  
Mreza.sobhiyeh@yahoo.com

**What processes are involved for a request to access data/document**

Up to one week after receiving the email, the requested documentation will be sent

**Comments**