

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

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Iran (Islamic Republic of)

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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 sobhie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Phone

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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

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Person responsible for scientific inquiries

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Latest degree

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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

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

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