

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparative evaluation for effect of perforator deep vein ligation in maturation and complications of side to side cubital arteriovenous fistula in kidney dialysis patients.

Protocol summary

Study aim

To determine the effect of perforator deep vein ligation in maturation and complications of side to side cubital arteriovenous fistula in kidney dialysis patients

Design

Randomized clinical trial with parallel control group, double blinded in 44 patients.

Settings and conduct

This randomized controlled clinical trial will be done on hemodialysis patients requires a cubital arteriovenous fistula referring to Mashhad Alavi Hospital in 2020-2021. Patients with proper conditions according to the randomized table (envelope method) are divided into two groups. The intervention is perforating deep vein ligation. Arteriovenous anastomosis will be brachiocephalic or radiocephalic with 4 to 6 millimeters length. Blindness is not possible for the active researcher in the design due to surgery performance. Patients under study, an active radiologist in the current design, an allocation to the groups and a statistical analyst are unaware from the grouping of patients .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent. Age > 18. Having general conditions for the creation of arteriovenous fistula. No history of hypotension. exclusion criteria: Dissatisfaction with the patient to continue the study. The absence of appropriate anatomical criteria for an appropriate side to side anastomosis (during surgery). End-side anastomosis based on anatomical criteria during surgery.

Intervention groups

Intervention group: Patients in this group will be subjected to perforator deep vein ligation with silk suture 3.0. Control group: In the control group, the perforator deep vein is not ligated.

Main outcome variables

Cephalic vein maturation and fitness for hemodialysis

using venous color doppler ultrasonography. Venous hypertension and steal syndrome. Occurrence of general complications of surgery including infection, seroma and hematoma.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080907001224N2**

Registration date: **2019-11-24, 1398/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-24, 1398/09/03**

Update count: **0**

Registration date

2019-11-24, 1398/09/03

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

05118525311

Email address

ravarih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation for effect of perforator deep vein ligation in maturation and complications of side to side cubital arteriovenous fistula in kidney dialysis patients.

Public title

evaluation for effect of perforator deep vein ligation in side to side cubital arteriovenous fistula in kidney dialysis patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent Age>18 Having general conditions for the creation of arteriovenous fistula No history of hypotension

Exclusion criteria:

Dissatisfaction with the patient to continue the study The absence of appropriate anatomical criteria for an appropriate side to side anastomosis. (during surgery) End-side anastomosis based on anatomical criteria during surgery

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of randomized numbers using statistical software. The envelope method is such that the envelopes are prepared and printed by a member of the surgical team (outside the research team), Random numbers with the help of statistical software inserted inside the envelope. Pocket doors will be closed and its contents are not visible from the outside. First, the purpose of the study is explained to the person who follows the conditions and the person, if desired, signs the informed consent form and removes the envelope and then opens it and, based on the contents of the envelope, enters into the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistical analyst will be unaware of the intervention and control groups. Blinding is not feasible for the active

researcher in the project due to surgery performance. Patients under study, active radiologist in the current design, allocator to the groups and statistical analyst are unaware of the patient group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of mashhad University of Medical Sciences

Street address

Vascular and endovascular research center, Alavi Hospital, Mashhad, emam reza 61

City

Mashhad

Province

Razavi Khorasan

Postal code

9173856693

Approval date

2019-02-26, 1397/12/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.760

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease, stage 5

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

cephalic vein maturation and Suitability for hemodialysis based on doppler ultrasonography.

Timepoint

1 week, 1 month, 3 months

Method of measurement

Maturation criteria based on the color doppler sonography is :flow >600 milliliter/Minute, cephalic length >10 Centimeters Or Two 4 Centimeters Segments; cephalic diameters>6 millimeters and < 5 millimeters Deep From Skin Surface

2

Description

Venous hypertension

Timepoint

1 week, 1 month, 3 months

Method of measurement

The excessive flow of intravenous retrograde leads to intravenous hypertension, which is accompanied by a change in the color of the blue, edema, dilatation of the veins and the color change of the organ in the physical examination.

3

Description

steal syndrome

Timepoint

1 week, 1 month, 3 months

Method of measurement

Steal syndrome refers to the diversion of arterial flow into another vascular bed, which does not meet the tissue needs of the target organ, and is manifested by symptoms such as pain, weakness, tissue loss and ulcers in the physical examination.

4

Description

General Surgical Complications

Timepoint

1 week, 1 month, 3 months

Method of measurement

Complications such as infection, seroma and hematoma are detected in a physical examination.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will undergo deep vein perforator ligation with silk suture 3.0.

Category

Treatment - Surgery

2

Description

Control group: Patients in this group will not undergo deep vein perforator ligation.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi vascular surgery hospital

Full name of responsible person

Hasan Ravari

Street address

Alavi vascular surgery hospital, Emam Reza street 61, Mashhad

City

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Province

Razavi Khorasan

Postal code

9173856693

Phone

+98 51 3804 7000

Email

ravarih@mums.ac.ir

2

Recruitment center

Name of recruitment center

Alavi hospital

Full name of responsible person

Hasan Ravari

Street address

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Postal code

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Phone

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Email

ravarih@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hasan Ravari

Street address

Vascular and endovascular research center, Alavi hospital Emam Reza 61

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Email

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Web page address

<http://mvasrc.mums.ac.ir/index.php/fa/43-persian-category>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hasan Ravari

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular Surgery

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The whole potential data is published after being unidentifiable.

When the data will become available and for how

long

The start of the access period will be 6 months after the publication of the results.

To whom data/document is available

Data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any analysis on the delivered data is allowed.

From where data/document is obtainable

Access to the study documentation will be possible by

contacting the Surgery Research Center at Alavi Hospital. The contact number and address, email and site center are listed in the previous sections

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

After submitting the request and approval to the Center's research committee, the documentation will be sent to the applicant within approximately 1 month.

Comments