

# 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**

Mashhad

#### **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**

Emam Reza 61

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9173856693

#### **Phone**

+98 51 3851 3258

#### **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

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9173856693

##### **Phone**

+98 51 3804 7000

##### **Email**

ravarih@mums.ac.ir

##### **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**

Vascular and endovascular research center, Alavi hospital, Emam Reza 61

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9173856693

**Phone**

+98 51 3851 3258

**Email**

ravarih@mums.ac.ir

## Person responsible for scientific 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**

Vascular and endovascular research center, Alavi hospital, Emam Reza 61

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9173856693

**Phone**

+98 51 3851 3258

**Email**

ravarih@mums.ac.ir

## Person responsible for updating data

**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**

Vascular and endovascular research center, Alavi hospital, Emam Reza 61

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9173856693

**Phone**

+98 51 3851 3258

**Email**

ravarih@mums.ac.ir

## 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**