

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of proximal arteriovenous fistula anastomosis side by side to end in patients with chronic renal failure

Protocol summary

Study aim

Comparison of side-to-side and side-to-end proximal arteriovenous fistula anastomosis in patients with chronic kidney failure.

Design

Randomized, parallel-group, single-blind, phase 3 clinical trial on 72 patients. In this study, block method with Sealed Envelope software will be used for randomization.

Settings and conduct

It is a single-blind clinical trial study that will be conducted in Valiasr Hospital in Arak city in 2022. In this study, patients who are candidates for arteriovenous fistula surgery who have the inclusion and exclusion criteria are included in the study. It is recorded in a checklist, this information includes age, sex, study group, bleeding, underlying disease, thrombosis, infection, pain, fistula maturation. These examinations are performed after surgery and It continues every two weeks until the fistula matures. Blinding is done in such a way that the performed technique is not known to the patient and each patient does not know about his anastomosis method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients who are candidates for arteriovenous fistula. exclusion criteria: liver disease, pregnancy

Intervention groups

In this study, the participants are divided into two groups A (end-to-side anastomosis) and group B (side-to-side anastomosis). In group A, the anastomosis was performed with the technique of connecting the end of the artery to the side of the vein in the proximal, and in group B, the anastomosis was performed with the technique of connecting the side of the artery to the side of the vein in the proximal.

Main outcome variables

Bleeding, Thrombosis, Pain at the fistula site, Fistula maturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044255N6**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Ali Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3276 7500

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of proximal arteriovenous fistula anastomosis side by side to end in patients with chronic renal failure

Public title
Arteriovenous fistula anastomosis in patients with chronic renal failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Arteriovenous fistula candidate patients
Exclusion criteria:
Hepatic disease pregnancy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to two groups A and B based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, by using the block method random number generation software, the randomization sequence will be produced according to the required sample size for two groups. In the beginning, all the modes that can arrange 2 letters A and B in a block of 8 are produced. Then a block will be selected randomly and by placement among the blocks, and the arrangement pattern in that block will be used to allocate the participants. Then this block will be placed in the main container and another block will be selected again. All these works will be done with a software called Sealed Envelope. In this method, concealment will also be observed. The concept of concealment is the unpredictability of assigning people to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Single blinded

Blinding description
Because this operation is performed while the patient is under anesthesia, the technique performed is not known to the patient, and each patient does not know his anastomosis method. But the project managers and outcome evaluators are aware of the type of anastomoses performed for patients and study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اراک

Street address

Payambar azam complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.ARAKMU.REC.1401.090

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

I13.11

ICD-10 code description

Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description

Bleeding

Timepoint

After surgery and every two weeks until the maturity of the fistula

Method of measurement

Physical examination

2

Description

maturation of fistula

Timepoint

After surgery and every two weeks until the maturity of the fistula

Method of measurement

Physical examination

3

Description

Pain at the fistula site

Timepoint

After surgery and every two weeks until the maturity of the fistula

Method of measurement

Visual Analogue Scale of pain

4

Description

Thrombosis

Timepoint

After surgery and every two weeks until the maturity of the fistula

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In the first group, arteriovenous anastomosis will be performed in 36 patients who are candidates for arteriovenous fistula with the technique of connecting the end of the artery to the side of the vein in the proximal part.

Category

Treatment - Surgery

2

Description

Second intervention group: In the second group, arteriovenous anastomosis will be performed in 36 patients who are candidates for arteriovenous fistula with the technique of connecting the end of the artery to the end of the vein in the proximal part.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dariush Poorakpur

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Payambar azam complex, Basij Sq., Sardasht Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Darioush Poorakpour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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