Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Street address
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
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Person responsible for updating data

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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