Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of efficacy and complications of end-side anastomosis of brachial artery to cubital perforating vein versus side-side brachiocephalic arteriovenous fistula formation in hemodialysis candidates at alzahra hospital

Protocol summary

Study aim

Both venous arteriovenous fistulas are surgically approved by two methods of anastomosis laterally and laterally. The aim of this study was to compare two methods of intravenous-arterial fistula formation of cephalic vein branch to brachial artery and brachiocephalic fistula. Baseline vascular access and complication of acetyl syndrome were performed in patients undergoing hemodialysis.

Design

In a clinical trial study, 85 patients undergoing arterial venous fistula placement were randomly divided in two groups of 42 and 43 patients. The first group was fed into the cephalic vein fistula to the adjacent brachial artery by side to side method and in the second group, the cephalic vein fistula was transferred to the brachial artery by end to side method. and the efficiency and duration of catheter operation were compared in two groups

Settings and conduct

Patients were recruited individually and were randomly assigned to two groups by using goitre (group one-group two). The first group underwent cephalic vein avf fistula and brachial artery laterally and the second group underwent cephalic vein avf fistula and lateral artery. Patients were followed up at the clinic by a specialist surgeon in three stages (postoperative day, one week postoperative and 12 weeks postoperative). The doctor did not know the type of surgery and the purpose of the study

Participants/Inclusion and exclusion criteria

Patient candidate for hemodialysis, candidate for elbow fistula, patient consent to participate in study, no intravenous injection in elbow for at least two weeks before Surgery and systolic blood pressure above 110 mm Hg before surgery

Intervention groups

Insertion of intravenous arterial fistula by two methods anastomosis laterally and laterally.

Main outcome variables

Measurement of blood flow at the fistula site Steel Syndrome and fistula Functional Deficiency

General information

Reason for update

Acronym

فیستول وریدی-شریانی

IRCT registration information

IRCT registration number: **IRCT20200217046525N1**
Registration date: **2020-02-21, 1398/12/02**
Registration timing: **retrospective**

Last update: **2020-02-21, 1398/12/02**
Update count: **0**

Registration date

2020-02-21, 1398/12/02

Registrant information

Name

Abbas Saroukhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3822 7000

Email address

saroukhaniabbas@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2016-08-31, 1395/06/10
Expected recruitment end date
2017-05-20, 1396/02/30
Actual recruitment start date
2016-09-14, 1395/06/24
Actual recruitment end date
2017-07-01, 1396/04/10
Trial completion date
2018-04-19, 1397/01/30

Scientific title
Comparison of efficacy and complications of end-side anastomosis of brachial artery to cubital perforating vein versus side-side brachiocephalic arteriovenous fistula formation in hemodialysis candidates at alzahra hospital

Public title
Comparison of the efficacy and side effects of intravenous-arterial fistula methods in hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with hemodialysis Patient with fistula implantation in elbow (including inappropriate vein or artery in wrist, previous failure of fistula in wrist) Patient's consent to participate in the study No intravenous injection into the elbow area at least two weeks before surgery Systolic blood pressure above 110 mm Hg before surgery
Exclusion criteria:
Fistula embolization due to underlying vascular problems (calcification and venous thrombosis) Inability to perform fistula without displacement due to venous topography
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **85**
Actual sample size reached: **85**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were recruited individually and were randomly with using spermatozoa, assigned to two groups(Group One-Group Two).The first group underwent cephalic vein avf fistula and brachial artery laterally and the second group underwent cephalic vein avf fistula and brachial artery.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients were not informed of their surgical procedure until the end of the study. Patients were followed up at the clinic by a specialist surgeon in three stages (postoperative day, one week postoperative and 12 weeks postoperative). The doctor did not know the type of surgery and the purpose of the study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Department of Surgery, Alzahra Hospital, Safeh Boulevard, Isfahan
City
Esfahan
Province
Isfehan
Postal code
8174675731
Approval date
2016-05-24, 1395/03/04
Ethics committee reference number
IR.mui.rec.1395.3.839

Health conditions studied

1

Description of health condition studied
Kidney failure
ICD-10 code
N18, N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Early efficacy of intravenous arterial fistula
Timepoint
Every two weeks until preparation for dialysis
Method of measurement
Physical examination by using checklists

Secondary outcomes

1

Description
Late efficacy of intravenous arterial fistula
Timepoint
Day after surgery, one week after surgery and 12 weeks after surgery
Method of measurement
Measurement of blood flow at the fistula site

2

Description
Steel Syndrome and Functional Deficiency
Timepoint
Day after surgery, one week after surgery and 12 weeks after surgery
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Intravenous-arterial fistula by anastomosis lateral to perforated branch of cephalic vein to brachial artery and brachiocephalic fistula
Category
Treatment - Surgery

2

Description
Intervention group: Creation of intravenous-arterial fistula by anastomosis side-by-side perforan branch of cephalic vein to brachial artery and brachiocephalic fistula
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Esfahan Alzahra Hospital
Full name of responsible person
Saroukhani Abbas
Street address
Al-Zahra Hospital, Sofeh Ave,Esfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hagjoy Javanmard, shagayeg
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Gostaresh Building No. 4, Isfahan University of Medical Sciences and Health Services., Hezar Jerib Ave.,Esfahan
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Saroukhani Abbas
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
At the time of publishing the data, no personal data of any participants will be published and only information on the outcome of the study will be reported.
When the data will become available and for how long
Documentation will be available 6 months after the end of the study.
To whom data/document is available
Study data will be available only to researchers working in academic institutions
Under which criteria data/document could be used
In order to receive data or other study documentation, a written request and the reason for the data need to be sent to the project manager.
From where data/document is obtainable
In order to receive study data refer to the study lead: Dr. Sarokhani: Address:Department of Surgery, Alzahra Hospital, Sofeh Boulevard, Isfahan phone number:-03138227000-09121813678 Fax: 03136684510 Email: saroukhaniabbas@yahoo.com
What processes are involved for a request to access data/document
To access the study data and documentation, the reason for the need for data and the type of data required should be sent to the Department of Surgery of Isfahan University of Medical Sciences through an official letter from the Institute of Research and Research.
Comments