Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of outcomes and functional results of placement of arteriovenous fistula with no-touch technique and comparison with conventional technique in patients who are candidate for hemodyalisis in Shariati hospital during 2017 to 2018

Protocol summary

Study aim

general goal: evaluation of outcome of an arteriovenous fistula between no touch and conventional technique in patients requiring hemodialysis who are referred to Shariati hospital in 2016-2018 practical goal: improvement of maturation time and primary patency in arteriovenous fistula in patients who are candidate for hemodialysis

Design

a randomized clinical trial based on a randomization list with parallel formation on 70 cases.

Settings and conduct

this study is conducted in Shariati hospital-Tehran University of Medical Sciences- Iran. the nurse who is responsible for the outcome evaluation is blind about the technique of surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients who were referred by nephrologists to vascular surgeons in order to placement of AVF. They had a vein diameter of more than 2 mm in distal and continuous patency of the upper limb. Exclusion criteria: 1) History of AVF placement 2) venous diameter less than 2 mm in diameter 3) absent venous flow in distal of upper limb 4) 3) systolic blood pressure less than 100 mmHg 5) Intention against participation in the study

Intervention groups

patients who are candidates for placement of arteriovenous fistula as a hemodialysis access. intervention in the case group is the placement of arteriovenous fistula by no-touch technique and it is a conventional technique in control group.

Main outcome variables

evaluation of patency rate of AVF in 2 weeks, 5 weeks and 3 months from the operation; time interval to functional start

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200505047307N1**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Alireza Mirsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2450

Email address

alidiza@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

2017-01-09, 1395/10/20

Actual recruitment end date

2018-12-31, 1397/10/10

Trial completion date

2019-07-01, 1398/04/10

Scientific title
Evaluation of outcomes and functional results of placement of arteriovenous fistula with no-touch technique and comparison with conventional technique in patients who are candidate for hemodyalisis in Shariati hospital during 2017 to 2018

Public title
Evaluation of No-touch technique for placement of arteriovenous fistula in hemodyalisis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who are candidate for routine hemodyalisis candidates for placement of arteriovenous fistula patent veins in all the course of it in upper limb
Exclusion criteria:
history of placement of arteriovenous fistula venous diameter of less or equal to 2 milimeter in ultrasonography absent blood flow in distal vessels diastolic blood pressure less than 100 mmHg intention against participation in the study
Age
From **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization was performed based on the table of random numbers. a specific point was chosen and numbers allocated to cases respectively from the top to the bottom of the table. patients with even numbers allocated to the intervention group (no-touch technique) and patients with odd numbers allocated to the control group (conventional technique).
Blinding (investigator's opinion)
Single blinded
Blinding description
patients are identified and randomized by code. the one who is responsible for collecting the outcome data is unaware of the type of operation that had been performed. the type of operation is known by the therapist who is the researcher as well.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Tehran university of Medical Sciences
Street address
tehran university of medical sciences central office, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2017-03-21, 1396/01/01
Ethics committee reference number
ir.tums.medicine.rec.1396.4260

Health conditions studied

1

Description of health condition studied
End stage renal disease
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
primary patency rate
Timepoint
2 and 4 weeks and 3 months after intervention
Method of measurement
based on physical examination

2

Description
time interval to start function
Timepoint
2 and 4 weeks and 3 months then monthly for 6 month
Method of measurement
physical examination and start to successful hemodialysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: placement of arteriovenous fistula by No touch technique. in this technique, the cephalic vein is dissected along with fat and surrounding soft tissue without a saline flush in vein.
Category
Treatment - Surgery

2

Description
Control group: arteriovenous fistula placement by conventional technique is done. the conventional technique consists of periadventitial dissection and saline flush in the vein.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Behnam Molavi
Street address
Shariati Hospital, Jalal ale ahmad highway
City
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1411713135
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences- deputy of research
Full name of responsible person
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Postal code
1411713135
Phone
+98 21 8490 1000
Email
shariatihosp@tums.ac.ir
Web page address
https://shariati.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences- deputy of research
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
Tehran University of Medical Sciences
Full name of responsible person
Alireza Mirsharifi
Position
assistant professor
Latest degree
Specialist
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
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
all related data will be published in an English manuscript
When the data will become available and for how long
after the publication, it will be unlimited
To whom data/document is available
based on the publisher`s policy
Under which criteria data/document could be used
for any scientific nonprofitable purposes
From where data/document is obtainable
to corresponding author through researchgate
What processes are involved for a request to access data/document
make a request in researchgate
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