

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 hemodialysis 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 hemodialysis in Shariati hospital during 2017 to 2018

Public title

Evaluation of No-touch technique for placement of arteriovenous fistula in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who are candidate for routine hemodialysis 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 millimeter 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

tehran

Province

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1411713135

Phone

+98 21 8490 1000

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shariatihosp@tums.ac.ir

Web page address

https://shariati.tums.ac.ir/

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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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

General Surgery

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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

Comments