

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

Evaluation of femoral tunnel hemodialysis catheter efficacy with different sizes

Protocol summary

Study aim

Evaluation of femoral tunnel hemodialysis catheter efficacy with different sizes

Design

This study is clinical trial and double blind. 50 patients candidate hemodialysis in Amiralmomenin hospital will enter this study. We will divide patients in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

This study is clinical trial and double blind. 50 patients candidate hemodialysis in Valiasr hospital will enter this study. Outcome assessor and analyzer not aware from grouping. Codes of group are available to analyzer and outcome assessor. Function and catheter effects are checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: There were no patients with the possibility of insertion of intravenous arteriovenous fistula or the possibility of insertion of Jugular and Subclavian Premium Catheter in the central vein catheterization, embedded candidate access hemodialysis of the lower limb. Exclusion criteria: The history of catheterization from femoral area or deep vein thrombosis in the lower extremity

Intervention groups

We put in one group 35 centimeter dialysis catheter and in another group we put 42 centimeter dialysis catheter

Main outcome variables

Function and complications of catheter types

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130410012973N3**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Amirreza Naimi

Name of organization / entity

Arak university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 1041

Email address

naimi-a@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of femoral tunnel hemodialysis catheter efficacy with different sizes

Public title

Evaluation of efficiency of dialysis tube of thigh with different sizes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who cant put arteriovenous fistula or Jugular and subclavian catheters

Exclusion criteria:
The history of catheterization from femoral area or deep vein thrombosis in the lower extremity

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Valiasr sq.

City

Arak
Province
Markazi
Postal code
3814957558
Approval date
2019-01-29, 1397/11/09
Ethics committee reference number
IR.ARAKMU.REC.1397.305

Health conditions studied

1

Description of health condition studied

End stage renal disese

ICD-10 code

N19

ICD-10 code description

Unspecified kidney failure

Primary outcomes

1

Description

Function and complication of different catheter

Timepoint

1 and 3 and 6 months after insertion catheter

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We put in a group a 35 centimeter dialysis catheter in femur (Bared.co).

Category

Treatment - Surgery

2

Description

Intervention group: We put in a group a 42 centimeter dialysis catheter in femur(Bared.co).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Amirreza Naimi
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Amiralmomenin hospital, Sardasht
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjmandzadegan
Street address
Vice chancellor for research, Payambar azam
complex, Basij square, Sardasht, Arak
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Web page address

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
Amirreza Naimi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Masomeh Farhangian
Position
Resident of surgery
Latest degree
Medical doctor
Other areas of specialty/work

General Surgery

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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