

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Study on the effect of Aspirin on patency rate of permanent hemodialysis catheters in ESRD patients

Protocol summary

Study aim

Investigating the effect Aspirin on hemodialysis permanent catheters

Design

parallel group, randomized, not blinded, phase 3 clinical trial on 74 patients.

Settings and conduct

All patients have medical records and are visited every 6 months. Patients who have not completed drug treatment or do not return will be excluded from the study. The correct and complete functioning of the catheter is evaluated in 6-month intervals. The change in the patency of permanent catheters following the intervention is the outcome of the study. The checklist is completed by the researcher to check the performance of the catheter.

Participants/Inclusion and exclusion criteria

mentally healthy patients with end stage kidney disease with right jugular catheter, who are willing to take the medication, and do not have a history of previous hemorrhagic disease and previous right jugular catheter.

Intervention groups

The study will be completed by clinical trial method with a sample size of 74 people in two groups of 37 patients of chronic renal failure with permanent right jugular catheter who refer to the mentioned dialysis center. The first group takes oral Aspirin 80 mg daily for one year and the second group is the control and does not receive any medication.

Main outcome variables

Extending the patency of permanent hemodialysis catheters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056873N1**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Mohammad farshad Zeinali baghini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2247 5984

Email address

mfzb0731@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-17, 1402/01/28

Expected recruitment end date

2024-04-16, 1403/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the effect of Aspirin on patency rate of permanent hemodialysis catheters in ESRD patients

Public title

Study on effect of Aspirin on permanent hemodialysis catheters patency rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

End stage kidney disease(ESRD) patients No history of psychiatric illness Consent to take the medication Right jugular permanent hemodialysis catheter Ability to communicate socially

Exclusion criteria:

Previous right jugular catheter Bleeding disorders history

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 74

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples to groups by random four block method with permutations (AABB-ABAB-ABBA-BABA-BAAB-BBAA) where the letter A represents the intervention group and B represents the control group. Each of the blocks is given a code from 1 to 6, and the researcher randomly selects a number from 1 to 6 and corresponding to the extracted code of the selected block and corresponding to the permutations of the selected block of samples will be assigned to two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of golestan university of medical sciences

Street address

Surgery department, 5azar hospital, 5azar street

City

Gorgan

Province

Golestan

Postal code

4917763681

Approval date

2023-01-25, 1401/11/05

Ethics committee reference number

IR.GOUMS.REC.1401.558

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Permanent hemodialysis catheter patency rate

Timepoint

Evaluating the catheters patency 6 and 12 months after the placement and aspirin prophylaxis

Method of measurement

The criterion for the proper functioning catheter is patients complete hemodialysis session using 200 cc per minute speed, which is confirmed by the complete dialysis checklist.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral aspirin 80 milligram tablet (from Jalinous company) will be taken daily for 1 year after right jugular permanent catheter placement, and the patency of the patient's catheter is evaluated by a checklist in two 6-month intervals from the start of use.

Category

Treatment - Drugs

2

Description

Control group: Patients with right jugular permanent hemodialysis catheter, who do not receive any medication in the period of one year, and like the intervention group, are evaluated by the checklist in two intervals of 6 months in terms of the correct functioning (patency) of the catheter.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

5azar hospital hemodialysis center

Full name of responsible person

Asiyeh Khalili

Street address

5azar hospital, 5azar street

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4917763681

Phone

+98 17 3115 3391

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pr-5azar@goums.ac.ir

Web page address

<https://goums.ac.ir/page/7816/%D8%AF%DB%8C%D8%A7%D9%84%DB%8C%D8%B2>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

professor nargesbeigom mirbehbehani

Street address

research affairs, second floor, central library, falsafi complex, shastkola road

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Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Fax

+98 17 3245 1657

Email

mirbeh@goums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Farshad Zeinali Baghini

Position

General surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Fax**Email**

Mfzb0731@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Mohammad farshad Zeinali baghini

Position

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Person responsible for updating data

Contact**Name of organization / entity**

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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

Yes - There is 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

All of the study's data will be available after deidentification

When the data will become available and for how long

The access period starts one year after publication

To whom data/document is available

data would be available for all researchers working in academic institutions and businesses

Under which criteria data/document could be used

There is no specific limitation.

From where data/document is obtainable

Dr Mohammad Farshad Zeinali Baghini, mobile: 09190257085, Email: mfzb0731@gmail.com

What processes are involved for a request to access data/document

After sending the request and explaining the reason for the request and the subject to be studied, the data will be provided to the requester as soon as possible.

Comments