

# 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

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 17 3115 3391

**Email**

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

**City**

Gorgan

**Province**

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

**Street address**

5azar hospital, 5azar street

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 21 2247 5984

**Fax****Email**

Mfzb0731@gmail.com

## Person responsible for scientific 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

**Street address**

5azar hospital, 5azar street

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 21 2247 5984

**Fax****Email**

Mfzb0731@gmail.com

## Person responsible for updating data

**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

**Street address**

5azar hospital, 5azar street

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 21 2247 5984

**Fax**

**Email**

Mfzb0731@gmail.com

## 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**