

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of Aspirin in prevention of permanent hemodialysis catheter thrombosis and increased internal jugular venous catheter survival

#### Protocol summary

##### Study aim

The effect of Aspirin in prevention of permanent hemodialysis catheter thrombosis and increased internal jugular Venous catheter survival

##### Design

A clinical trial with a control group, Based on 114 subjects In a sample of two groups of 57 patients

##### Settings and conduct

In This Study, 114 Patients In Ardabil Fatemi Hospital Were Divided In Two Groups Of Control And Intervention. 57 Patients Were Treated With Aspirin And 57 Patients Were Placed In The Control Group. The Average Useful Time Of The Gugular Vein Catheter Was Recorded After Placement And Compared Between two groups. To Examine Quantitative Data, Independen T-test And For Qualitative Data, Chi Square Test And Fisher's Exact Test Will Be Used If Necessary.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria:End Stage renal disease patients requiring permanent hemodyalisis catheter And Patients candidate For hemodyalisis catheter replacemen  
Exclusion Criteria: The catheter malfunction since the beginning, Catheter site infection, Previous coagulation abnormalities in patients, and any contraindication for Aspirin usage.

##### Intervention groups

Intervention Group: 57 Person in intervention group will be treated from day after catheter insertion with Aspirin 80 mg Daily (All Patients Will Use Aspirin From A Pharmaceutical Company). Control group: 57 Person In controls group will Be provided from the day after the placement of catheter with placebo (Placebo From The Razi Pharmaceutical Company, And 4800 Tablets Will Be Required For A Period Of 3 Months For 60 Patients. Placebo In Terms Of Color, Shape And Size Is The Sames) Will Be Treated.

##### Main outcome variables

Jugular Vein Catheter Thrombosis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181128041785N1**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **retrospective**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

##### Registration date

2019-02-24, 1397/12/05

##### Registrant information

##### Name

Mohammad bagher Didarshetaban

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3333 7710

##### Email address

mb.didarshetaban@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Aspirin in prevention of permanent hemodialysis catheter thrombosis and increased internal jugular venous catheter survival

#### Public title

Effect of Aspirin in prevention of permanent hemodialysis catheter thrombosis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

ESRD Patient Requiring Permanent Hemodialysis  
Catheter Patients Candidate For Hemodialysis Catheter Replacement

##### Exclusion criteria:

Blood loss Requiring Either Hospitalization Or Transfusion In The Previous 3 Months Advanced Proliferative Diabetic Retinopathy Life Expectancy < 12 Months Because Of Advanced Organ-Systemic Disease Or Malignancy Uncontrolled Systolic Blood Pressure, BP > 200 mmHg Or Diastolic BP >110 mmHg On Three Different Occasions In A Period Of 2 Weeks Platelet count < 100,000 INR > 1.3 Partial Thromboplastin Time 5 Seconds Longer Than Control Patients Receiving Dipyridamole ,Sulfinpyrazone ,Ticlopidine , Clopidogrel ,Or Nonsteroid Anti-inflammatory Drugs All Bleeding Episode After Aspirin Use Leading HB Loss>1 Gr/Dl Catheter Dysfunction From Insertion Catheter Site Infection Catheter Replacement More Than 3 Times Previous Coagulopathy

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 114

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ardabil University of medical

sciences

#### Street address

No. 1, Moallem St, Ardabil

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5613843793

#### Approval date

2018-12-27, 1397/10/06

#### Ethics committee reference number

IR.ARUMS.REC.1397.190

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

Catheter Thrombosis

#### Timepoint

At the begining, Catheter dysfunction in first 3 month

#### Method of measurement

Direct vision of catheter thrombosis, venous Doppler sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group: 57 Person In Intervention Group Will Be Treated From Day After Catheter Insertion With Aspirin 80 mg Daily (All Patients Will Use Aspirin From A Pharmaceutical Company).

#### Category

Prevention

### 2

#### Description

Control group: 57 Person In controls Group Will Be Provided From The Day After The Placement Of Catheter With Placebo (Placebo From The Razi Pharmaceutical Company, And 4800 Tablets Will Be Required For A Period Of 3 Months For 60 Patients. Placebo In Terms Of Color, Shape And Size Is The Sames) Will Be Treated.

**Category**  
Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Fatemi Hospital  
**Full name of responsible person**  
Vakili Mohammad MD  
**Street address**  
Fatemi Hospital, Shariati St  
**City**  
Ardabil  
**Province**  
Ardabil  
**Postal code**  
5614733775  
**Phone**  
+98 45 3323 2670  
**Fax**  
+98 45 3323 2670  
**Email**  
Mb.didarshetaban@arums.ac.ir  
**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
پروانه نفتچی  
**Street address**  
Ardabil university of medical sciences, Daneshgah St  
**City**  
Ardabil  
**Province**  
Ardabil  
**Postal code**  
5618985991  
**Phone**  
+98 45 3352 2247  
**Email**  
info@arums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ardabil 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**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Amin Reza zadeh  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Fatemi Hospital, Shariati St  
**City**  
ardabil  
**Province**  
Ardabil  
**Postal code**  
5614733775  
**Phone**  
+98 45 3323 2670  
**Email**  
Mb.didarshetaban@arums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Amin Reza zadeh  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Fatemi Hospital, Shariati St  
**City**  
Ardabil  
**Province**  
Ardabil  
**Postal code**  
5614733775  
**Phone**  
+98 45 3323 2670  
**Email**  
Mb.didarshetaban@arums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Amin Rezazadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Fatemi Hospital, Shariati St

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5614733775

**Phone**

+98 45 3323 2670

**Email**

Mb.didarshetaban@arums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

After unidentified people, the demographic data and the duration of the catheter performance will be used to evaluate the effect of aspirin.

**When the data will become available and for how long**

Starting the access from 2020

**To whom data/document is available**

Access will be free for every one.

**Under which criteria data/document could be used**

Statistical analyzes are allowed on data.

**From where data/document is obtainable**

Will be contact by Dr Amin Rezazadeh Email.

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

It take a total of one month.

**Comments**

No other information is required.