

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
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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
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Person responsible for scientific inquiries

Contact

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Position
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Specialist
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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

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Phone

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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.