Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of aspirin consumption on permanent Internal Jugular dialysis catheter patency in End Stage Renal Disease (ESRD) patients

Protocol summary

Study aim

The effect of aspirin consumption on permanent internal jugular catheter patency in patients with End Stage Renal Disease (ESRD) referred to Bahman Hospital and Shafa center for dialysis in Zanjan city

Design

Clinical trial with control and intervention groups, one side blind, randomized, phase 3 on 84 patients. Spss 26 software was used for randomization.

Settings and conduct

84 dialysis patients with permanent internal jugular catheter referred to Bahman Hospital and Shafa Dialysis Center in Zanjan are included in the study and randomly divided into two control and intervention groups. The first group is given placebo and the second group is given aspirin daily for 6 months along with dialysis treatment. The required information is recorded based on the patients' files. In the end, by analyzing the data, the effect of aspirin on the survival time of the catheter is determined.

Participants/Inclusion and exclusion criteria

entry conditions : 1)the patient has ESRD 2)at least one month should be passed since the start of hemodialysis maintenance 3)at least one month & at most one year should be passed since the installation of the internal jugular permcath 4)there should'nt have any contraindication for normal use of Aspirin No entry conditions: 1)current Aspirin use at the time of entry in the study 2)the presence of known underlying diseases that increase the risk of thrombosis 3)use of anticoagulants 4) use of Tarulac 5)catheter infection before onset of study 6)imperfection of the patient`s file regarding the items required 7)patient disfavor to enter the study

Intervention groups

In the intervention group, aspirin 80 mg and in the control group, placebo is given to the patients daily for 6 months, and the survival time of the catheter is recorded in both groups.

Main outcome variables

Survival time of permanent internal jugular dialysis catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220110053680N1**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **retrospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name
Bahareh Hajisalimi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 912 341 5640
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of aspirin consumption on permanent Internal Jugular dialysis catheter patency in End Stage Renal Disease (ESRD) patients

Public title
effect of aspirin on permanent Internal Jugular dialysis catheter patency
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has ESRD and Glomerular Filtration Rate (GFR) <15ml / min / 1.73 m^2. At least one month should be passed since the start of hemodialysis maintenance. At least one month and at most one year should be passed since the installation of the internal jugular permcath . There shouldn't have any definitive contraindication for normal use of aspirin
Exclusion criteria:
Current aspirin use at the time of entrance in the study Presence of a known underlying disease that increases the risk of thrombosis (lupus, antiphospholipid syndrome, presence of nephrotic syndromes) use of anticoagulants (warfarin, heparin, apixaban, rivaroxaban, plavix) use of Tarulac Catheter infection before beginning the study Incomplete patient document regarding the items required in the study Patient disfavor with inclusion in the study
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be randomly assigned to one of the two control and intervention groups, which will use Excell 2016 edition for randomization. To do this, we enter 42 numbers 1 and 42 numbers 2 in the first column. Then in the second column we use the RAND () function and generate 84 random numbers. We arrange the data based on, column including values of random numbers (ascending or descending). With this sorting, the order of numbers 1 and 2 in the first column will also change and be placed randomly. Based on the order of appearance of numbers 1 or 2 and according to the list of names of people included in the study, the samples are assigned to 2 groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The main researchers and data analysts will know which group each of the samples are in, but the samples themselves will be told that the drug given to them is aspirin, and the side effects of aspirin will be explained to the patients and consent Admission to the study is taken. Therefore, the samples will not know which control or intervention group they are in. The main researchers are responsible for data collection, and in this study, the only communication will be between the main researchers and the patients, and other than the person responsible for data analysis, no other people will have a role in this study.
Placebo
Used
Assignment
Other
Other design features
84 samples are randomly divided into two control and intervention groups and 80 mg aspirin is given to the intervention group and placebo to the control group daily for 6 months.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Zanjan , Azadi Blvd , Research and Technology Vice-Chancellor, 1st Floor , Ethics Committee in Biomedical Research
City
Zanjan
Province
Zanjan
Postal code
۴۵۱۵۶۱۳۱۹۱
Approval date
2022-07-13, 1401/04/22
Ethics committee reference number
IR.ZUMS.REC.1401.109

Health conditions studied

1

Description of health condition studied
end stage renal disease (ESRD) , patency of internal jugular permcath , aspirin consumption
ICD-10 code
Z45.2

ICD-10 code description
Encounter for adjustment and management of vascular access device

Primary outcomes

1

Description
Duration of internal jugular permcath patency
Timepoint
Weekly
Method of measurement
Number of days that permcath has function during the 6 month of the study

Secondary outcomes

1

Description
duration of time that patient has suffered from End Stage Renal Disease (ESRD)
Timepoint
At onset of study
Method of measurement
Number of months passed since the diagnosis of ESRD and onset of hemodialysis

2

Description
History of heart failure
Timepoint
At onset of the study
Method of measurement
Ejection Fraction (EF) less than 50% according to echocardiography record in patient's file

3

Description
Hypertension
Timepoint
At onset of the study and in patients with hypertension, weekly until the end of the study
Method of measurement
Systolic blood pressure (SBP) ≥ 140 mmHg or Diastolic blood pressure (DBP) ≥ 90 mmHg according to patient's file

4

Description
Diabetes mellitus
Timepoint
At onset of the study
Method of measurement
Fast Blood Sugar (FBS) ≥ 126 mg/dl according to patient's file

5

Description
Age
Timepoint
At onset of the study
Method of measurement
Asking from patient

6

Description
Sex
Timepoint
At onset of the study
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: Receive 80 mg aspirin orally, once a day , for 6 months, made by Parsdarou Company The survival time of the catheter is recorded from the time of the start of Aspirin use to the failure of the catheter. The evaluation of the catheter function and the continuation of the patient's medication will be weekly.
Category
Treatment - Drugs

2

Description
Control group: receive placebo orally, 1 tablet per day, for 6 months, made by Faculty of Pharmacy, Zanjan University of Medical Sciences with formulation of : Avicel 102 (0.17g) + HPMC (0.004g) + Propylene glaco (0.005g) + Titanium dioxide (0.0001g) + FD & C yellow No 10 (0.00001g) + talc (0.0014g) The survival time of the catheter is recorded from the time of the start of placebo use to the failure of the catheter. The evaluation of the catheter function and the continuation of placebo consumption in the patient will be weekly.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Bahman Hospital
Full name of responsible person
Ayoub Pezeshki
Street address
Bahman 22 Highway - Opposite to the Police Headquarters - Punak Town - Behind Roozbeh University - Bahman Zanjan Hospital
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2

Recruitment center
Name of recruitment center
Zanjan Shafa Kidney Patients Support Association
Full name of responsible person
Bahareh Hajisalimi
Street address
Azadegan town, end of Farvardin street, central building
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Samad Nadri
Street address
Karmandan Town - End of Haj Ahmad Mahdavi Street - Zanjan University of Medical science - Medical faculty
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Phone
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Fax
+98 24 3344 9553
Email
medicine@zums.ac.ir
Web page address
https://medical.zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Hanieh Davoodi
Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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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