# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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)
**Phone**
+98 912 341 5640
**Email address**
bahareh77@zums.ac.ir

**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
**City**
Zanjan

**Province**
Zanjan
**Postal code**
4515653346
**Phone**
+98 24 3303 9999
**Fax**
+98 24 3303 9237
**Email**
info@zbh.ir
**Web page address**
https://zbh.ir/

**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
**City**
Zanjan
**Province**
Zanjan
**Postal code**
4513733678
**Phone**
+98 24 3341 1203
**Fax**
+98 24 3341 1205
**Email**
info@zanjankf.org
**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
**City**
Zanjan
**Province**
Zanjan
**Postal code**
4513956111
**Phone**
+98 24 3314 0201
**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
**Street address**
Karmandan Town - Phase 2 - West 4th Street - No. 813 - Unit 3
**City**
Zanjan
**Province**
Zanjan
**Postal code**
4513994943
**Phone**
+98 24 3344 3965
**Email**
md.101.2512@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Nadia Agharafiei
**Position**
Medical Intern
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner

**Street address**
Shahre Ziba neighborhood - Shahre Ziba square - Ashouri street - end of Bahar alley - No.16 - Unit 3
**City**
Tehran
**Province**
Tehran
**Postal code**
1486946878
**Phone**
+98 21 4435 9882
**Email**
nadia.agharafiei@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Bahareh Haji Salimi
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Above Valiasr Square - Hazrat Valiasr Medical Education Center
**City**
Zanjan
**Province**
Zanjan
**Postal code**
45157-77978
**Phone**
0098 24 33770801-4
**Email**
baharehajisalimi@yahoo.com

## 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