# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluating the effects of Warfarin on permacath function in hemodialysis patients

### Protocol summary

**Study aim**
Evaluating the effect of Warfarin on hemodialysis catheter failure prevention

**Design**
Randomized clinical trial with control group , randomized with random allocation software, population in each group is 43

**Settings and conduct**
This study is going to take place in Alzahra hospital in Isfahan city. All of the studied patients undergo standard surgical procedure for the hemodialysis permanent catheter embedding and a skilled target surgeon perform all of the procedures.The resident of general surgery is going to follow the patients.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:Age above 18 years-old,patients who were a candidate for second time permcath placement.Informed consent for participation. Exclusion criteria:History of major hemorrhages, progressive diabetic retinopathy, less than 12 months of life-expectancy because of systemic disease or malignancies, poorly controlled hypertension, platelet less than 100000,INR≥1.3,PTT≥ 5 folds than the normal, hypersensitivity to Warfarin, active peptic ulcer, pregnancy or lactation,documented aortic aneurysm

**Intervention groups**
Treatment with Warfarin was initiated for the participants in the intervention group (Warfager tablet, Hoger Danesh Daroo company,Iran) as soon as the cessation of the surgical procedure and its dose was adjusted in order to set INR in the range of 1.5-2.The control group did not receive any anticoagulants and discharged after the surgery. The intervention group received IV Heparin initially.All of the used permcaths in this study are the same and from the Arrow company made in Ireland. INR was checked monthly in order to adjust the warfarin dose if needed.

**Main outcome variables**
Finding a method to reduce the thrombosis risk and catheter failure.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200516047461N1**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **retrospective**

Last update: **2020-05-20, 1399/02/31**
Update count: **0**

**Registration date**
2020-05-20, 1399/02/31

**Registrant information**
**Name**
parto nasri
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3620 2088
**Email address**
parto.nasri@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-01-05, 1398/10/15

**Expected recruitment end date**
2020-04-08, 1399/01/20

**Actual recruitment start date**
2020-01-05, 1398/10/15

**Actual recruitment end date**
2020-04-08, 1399/01/20

**Trial completion date**

2021-03-05, 1399/12/15

**Scientific title**
Evaluating the effects of Warfarin on permacath function in hemodialysis patients

**Public title**
The effects of Warfarin on permacath function
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients who were a candidate for the second time embedding of permanent arteriovenous catheters Informed consent to participate in the study Age above 18 years old
**Exclusion criteria:**
History of major hemorrhages (requiring blood transfusion, retroperitoneal or intracranial hemorrhage, inducing hypovolemia, leading to more than two units decrease in hemoglobin) within the previous three months Progressive diabetic retinopathy Less than 12 months of life-expectancy because of systemic disease or malignancies Poorly controlled hypertension (systolic blood pressure>200 mmHg or diastolic blood pressure>100 mmHg measured three times within two weeks) Absolute platelet count less than 100000 International normalized ratio (INR)≥1.3 Partial thrombin time (PTT)≥ 5 folds than the normal range Hypersensitivity to Warfarin Active peptic ulcer Pregnancy or lactation Documented aortic aneurysm
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **86**
Actual sample size reached: **86**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The study population divided into two groups (intervention and control ) by using Random Allocation software.
**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 Isfahan university of medical sciences
**Street address**
Hezar Jerib Street,Isfahan university of medical sciences
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2019-04-20, 1398/01/31
**Ethics committee reference number**
IR.MUI.MED.REC.1398.266

## Health conditions studied

### 1

**Description of health condition studied**
Chronic kidney disease
**ICD-10 code**
N18
**ICD-10 code description**
Chronic kidney disease (CKD)

## Primary outcomes

### 1

**Description**
Permcath function
**Timepoint**
In every hemodialysis session
**Method of measurement**
Catheter clotting defined as the gross visible occlusion of the catheter or the dialysis performance with less than 250 ml per minute velocity

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: According to the inclusion and exclusion criteria 86 patients (43 in the intervention group and 43 patients in the control group) recruited. The patients are a candidate for second-time permcath placement. All of the studied patients undergo standard surgical procedure for the permanent hemodialysis catheter embedding a skilled target surgeon performs all

of the procedures and all of the embedded catheters are from the Arrow Company made in Ireland. In the next step, treatment with warfarin initiate for the participants in the intervention group (Warfager tablet, Hoger Danesh Daroo company made in Iran) as soon as the cessation of the surgical procedure and its dose will be adjusted in order to set INR in the range of 1.5-2. Furthermore, INR will be checked monthly in order to adjust the warfarin dose if needed, and prevent from any probable warfarin-induced hemorrhagic event. The participants were discharged on the next day of catheter embedding and were re-visit monthly until a year following the surgery to a requirement for the excision of the catheter. Besides, in order to initiate warfarin therapy, the baseline INR was recorded from the laboratory tests of the patients taken before the surgical procedure of permanent catheter embedding.

**Category**

Prevention

**2**

**Description**

Control group: 43 Patients in the control group undergo a standard surgical procedure for the permanent hemodialysis catheter embedding. A skilled target surgeon performs all of the procedures, and all of the embedded catheters are from the Arrow Company made in Ireland. The control group did not receive any anticoagulants and discharged after the surgery. The participants will be re-visited monthly until a year following the surgery to a requirement for the excision of the catheter.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Al-zahra hospital

**Full name of responsible person**

Milad Golshani nasab

**Street address**

Soffeh Blvd.

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8174675731

**Phone**

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milad.golshani@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Vice-Chancellery for Research and Technology

**Street address**

Hezar Jerib street

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international@mui.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Vice-Chancellery for Research and Technology

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Milad Golshani nasab

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

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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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
After making the patients' personal information unrecognizable, the data can be published and shared.

**When the data will become available and for how long**
Three months after publishing the results, the data will be accessible.

**To whom data/document is available**
Medical researchers

**Under which criteria data/document could be used**
The documented data is going to be presented to the Vice-Chancellery for Research and Technology of Isfahan University of medical sciences and the publisher journal.

**From where data/document is obtainable**
The Vice-Chancellery for Research and Technology of isfahan university of medical sciences

**What processes are involved for a request to access data/document**
Referring to the Vice-Chancellery for Research and Technology of Isfahan University of medical sciences and having a confirmation from the chief executor of the research the documentation can be accessible.

**Comments**