

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 permacath 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, $INR \geq 1.3$, $PTT \geq 5$ 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 permacaths 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

Isfahan

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.

City

Isfahan

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Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

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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Province

Isfahan

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8174673461

Phone

+98 31 3792 3071

Email

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

Street address

Hezar Jerib street

City

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Province

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Postal code

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Phone

+98 31 3668 5555

Email

milad.golshani@gmail.com

Person responsible for scientific 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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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

Person responsible for updating data

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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