

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study on the efficiency of Drug-coated balloon with non-medicinal balloon in the efficiency of intravenous artery fistula in hemodialysis patients over a six-month period

Protocol summary

Study aim

A comparative study on the efficiency of the Drug-coated balloon with non-medicinal balloon in the efficiency of intravenous artery fistula in hemodialysis patients over a six-month period

Design

This study is a non-blinded clinical trial. The study population will be included all patients with chronic renal failure refer to Imam Reza hospital of Kermanshah city. 50 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

Settings and conduct

This study which will be conducted in Imam Reza hospital of Kermanshah city is non-blinded one. At the beginning of the study, blood pressure is recorded in a checklist in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic renal failure
Exclusion criteria: Patients who there is no possibility of fistulate during surgery for them

Intervention groups

In the first intervention group, surgery is performed through an angioplasty medicinal balloon.

Main outcome variables

Blood pressure, infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N112**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the efficiency of Drug-coated balloon with non-medicinal balloon in the efficiency of intravenous artery fistula in hemodialysis patients over a six-month period

Public title

Comparison of the efficiency of the Drug-coated balloon with non-medicinal balloon in the efficiency of the intravenous artery fistula in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic renal failure

Exclusion criteria:

Patients who there is no possibility of fistulate during surgery for them

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

ir.kums.rec.1397.518

Health conditions studied

1

Description of health condition studied

Patients who are treated with hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Renal Failure

Primary outcomes

1

Description

Blood pressure

Timepoint

The day after surgery, one week later and 3 weeks later

Method of measurement

using blood pressure measurement

2

Description

Infection

Timepoint

The day after surgery, one week later and 3 weeks later

Method of measurement

By the doctor

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, surgery is performed through an angioplasty balloon. In the second intervention group, surgery will be performed through non-pharmacological angioplasty.

Category

Treatment - Surgery

2

Description

In the second intervention group, surgery will be performed through non-pharmacological angioplasty.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital, Parastar Boulevard

Full name of responsible person

Siroos Amiri

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

siroosamiri1348@gmail.com

Position

Resident of Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
Beheshti

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fnajafi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Siroos Amiri

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad reza Sobhiyeh

Position

Faculty Member of Kermanshah University of Medical
Sciences

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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mrza.sobhiyeh@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Siroos Amiri

Position

Resident of Surgery

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments