

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative Survey of efficacy of two type hemodialysis catheter with different medical factors in dialysis patient

Protocol summary

Study aim

A comparative survey of efficiency of two type hemodialysis catheter with different medical factors in dialysis patient

Design

The study is a clinical trial. During one year, all dialysis patients, including 185 patients, were introduced to the Imam Center for continuous hemodialysis catheter insertion, which were randomly divided into two groups: catheter, Vector flow, and Palindrom. The phase of clinical trial in This current study does not apply. The intervention groups are random and can not be blinded.

Settings and conduct

For patients in the operating room, a surgeon underwent sonography of a continuous hemodialysis catheter in the internal jugular vein and was followed up for one year and studied for duration and length of life.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent of patients and patients undergoing hemodialysis candidate dialysis;
Exclusion Criteria: non-cooperation for follow-up

Intervention groups

In this study, the patients were divided into two groups and one group of catheter Vector flow and the other group were placed in the catheter of the Palindrome and compared with the catheter longevity

Main outcome variables

Lifetime of hemodialysis catheter, The effect of individual factors on catheter longevity, spent costs, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180223038837N2**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Mohammad Reza Sobhiyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-09-23, 1397/07/01

Trial completion date

2018-09-23, 1397/07/01

Scientific title

A comparative Survey of efficacy of two type hemodialysis catheter with different medical factors in dialysis patient

Public title

Efficiency of two type hemodialysis catheter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All dialysis patients who are candidates for hemodialysis

Exclusion criteria:

Failure to collaborate for follow-up

Age

From **27 years** old to **94 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **185**

Actual sample size reached: **185**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 185 patients with entry conditions are selected by available sampling method and then randomly assigned randomly using the random numbers table in one of the two groups of vector flow and palindrom

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

Kermanshah, Sorkhe Layezh, Nursing Blvd, Imam Reza Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Approval date

2018-10-12, 1397/07/20

Ethics committee reference number

IR.KUMS.REC.1397.519

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

18.5

ICD-10 code description

End stage kidney disease: on dialysis

Primary outcomes

1

Description

Catheter Longevity

Timepoint

One year follow up

Method of measurement

Checklist is provided

Secondary outcomes

1

Description

Catheter Longevity

Timepoint

one year

Method of measurement

Evaluation of dialysis quality

2

Description

The Effect of Individual Characteristics on Catheter Longevity

Timepoint

One year

Method of measurement

Documentation file

Intervention groups

1

Description

Intervention group 1: This group consists of patients who have been placed in a catheter with a vector flow. The catheter is a continuous hemodialysis catheter inserted in the operating room by the surgeon and under sonography in the jaguar vein.

Category

Treatment - Surgery

2

Description

Intervention group 2: This group consists of patients who have been placed under the patch catheter. The palindrome catheter is a permanent hemodialysis catheter that is inserted into the operating room by the surgeon in the jaw gland ultrasound in the jaguar vein.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohammadreza Sobhie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Administrative building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah, City, Iran

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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

Mohammadreza Sobhie

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the case of the participants data file, three months after the publication of the article, and after unidentification of the persons, the request can be sent by email

When the data will become available and for how long

Three months after the publication of the article, upon request by email, there is a possibility to post

To whom data/document is available

Only scholars working in academic and scientific institutions

Under which criteria data/document could be used

The name of the first author of the study is required in an extracted article from the study data. In this case, it is possible to perform any statistical analysis

From where data/document is obtainable

Correspondence by email with the Doctor

Mohammadreza

Sobhie. Email: mreza.dobhie@yahoo.com

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

Up to one week after receipt of the email, the requested documentation is sent

Comments