Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical outcome comparison between two methods of blind and under flouoroscopic hemodialysis catheter insertion

Protocol summary

Summary

Aims of this study are functional and complications comparison between two methods of hemodialysis catheter insertion(under fluoroscopic and traditional). Target sample size is established according to power 80% and confidence 95% and other studies 128 patients. In a randomized clinical trial with parallel plan,128 patients that have inclusion criteria after wisdom permission are allocated in two groups(under fluoroscopic and traditional). Randomizing process are doing by random blocs planning. Questionnaire is filled end of next day and 30th day after operation. Function and complications are compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120329181N3**
Registration date: **2016-12-25, 1395/10/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name
Nasser Malekpour Alamdari
Name of organization / entity
Shaid Behesht University of Medical Sciences
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Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Modarres hospital

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical outcome comparison between two methods of blind and under flouoroscopic hemodialysis catheter insertion

Public title

Outcome and complications comparison between two methods of hemodialysis catheter insertion

Purpose

Prevention

Inclusion/Exclusion criteria

Patients that need hemodialysis and don't have any contraindication for surgery are recruited in this study. Exclusion criteria: coagulopathy; uncontrolled cardiopulmonary disease that make patient unable to tolarate surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Commity of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Danshju blvd., Velenjak

City

Tehran

Postal code

Approval date

2016-11-29, 1395/09/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.553

Health conditions studied

1

Description of health condition studied

Chronic kidney disease on hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Catheter function

Timepoint

First and 30th day

Method of measurement

Easily possibility of hemodialysis

Secondary outcomes

1

Description

Hematoma

Timepoint

During Insertion

Method of measurement

Physical Exam,Chest Radiography

2

Description

Pneumothorax

Timepoint

During Insertion

Method of measurement

Physical Exam,Chest Radiography

3

Description

Hemothorax

Timepoint

During Insertion

Method of measurement

Physical Exam,Chest Radiography

4

Description

Vessel Injury

Timepoint

During Insertion

Method of measurement

Physical Exam,Chest Radiography

Intervention groups

1

Description

In intervention group under fluoroscope at first the wire is navigated through internal jugular vein and park in IVC,then cahteter pass on the wire till cavoatrial junction.

Category

Treatment - Surgery

2

Description

In control group from internal jugular vein wire and catheter on the wire are navigated into SVC.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Nasser Malekpour Alamdari
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nasser Malekpour Alamdari
Street address
Danshju Ave Velenjak
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty