Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the efficacy of Taurolock and Saline 5% in prevention of hemodialysis catheter infection and dysfunction

Protocol summary

Study aim

The aim of this study is to evaluate the effect of Taurolock and salin5% as lock solutions for prevention of catheter dysfunction and hemodialysis tunneled-catheter related infection.

Design

This is a controlled single-blinded clinical trial study will be conducted on 68 individuals requiring hemodialysis. After coordination and obtaining informed consent, the patients (n=34per group) will be randomly assigned into two groups of salin5% and taurolock and will be follow up for 3 months.

Settings and conduct

From patients with chronic kidney disease requiring dialysis with tunneled hemodialysis catheter referring to hemodialysis center of Golestan hospital, Ahvaz, Iran total of 68 patients will be selected and randomly divided into 2 groups.In the first group, salin5% will be injected into the lumen of the catheter after each hemodialysis session and catheter locked. In the second group, will be used Taurolock solution as lock antibiotic. The patients will not know about type of treatment and grouping and thus until the end of trial the study will be remained single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, patients with chronic kidney disease requiring dialysis with tunneled hemodialysis catheter, Consent to participate in the study; Exclusion criteria: using the central venous catheters for anything other than haemodialysis

Intervention groups

In the first group, salin5% will be injected into the lumen of the catheter after each hemodialysis session and catheter locked. In the second group, will be used Taurolock solution as lock antibiotic.

Main outcome variables

Catheter infection and catheter dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190304042918N1**
Registration date: **2019-04-27, 1398/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**
Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name
Maryam Afkane
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3333 5935
Email address
afkane.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-15, 1397/12/24

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Taurolock and Saline 5% in prevention of hemodialysis catheter infection and dysfunction

Public title
Effect of Taurolock in prevention of catheter infection and dysfunction
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic kidney disease requiring dialysis with tunneled hemodialysis catheter Age over 18 years Consent to participate in the study
Exclusion criteria:
Using the central venous catheters for anything other than haemodialysis
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups of experimental and control. Each patient is given a number from 1 to 64 and assignment of patients into the study groups will be done by table of random numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients will not know about grouping and type of intervention (receiving either Taurolock or Saline). Taurolock and saline are placed in the same package (with special code) so that the participants do not understand which group they belong to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
61355393
Approval date
2018-09-15, 1397/06/24
Ethics committee reference number
IR.AJUMS.REC.1397.412

Health conditions studied

1

Description of health condition studied
Catheter-related infection
ICD-10 code
A49.9
ICD-10 code description
Bacterial infection, unspecified

Primary outcomes

1

Description
Catheter-related infection
Timepoint
After each session hemodialysis for 3 months
Method of measurement
Clinical examination of infection and blood culture

2

Description
Catheter-related dysfunction
Timepoint
In each session of hemodialysis for 3 months
Method of measurement
Blood flow less than 250 cc/min through the CVC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Salin5% will be injected into the lumen of the catheter after each hemodialysis session and catheter locked
Category
Prevention

2

Description

Intervention group: In this group, will be used Taurolock (TauroLock™-Hep 500®) solution as lock antibiotic. Taurolock vial containing taurolidine (antimicrobial agent), 500 units heparin per mL and citrate 4%. lock solution will be injected into the lumen of the catheter after each hemodialysis session and catheter locked

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Ali Ghorbani

Street address

Golestan Hospital, Faevardin Ave., Golestan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Ghirbani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

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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)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available