

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+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.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733118

**Phone**

+98 61 3374 3001

**Email**

Ali.ghorbani.001@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
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**Phone**

+98 61 3373 8383

**Email**

badavim@yahoo.com

**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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Ali.ghorbani.001@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

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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