

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of using Cloxacillin as an "Antibiotic Lock Solution" versus placebo on prevention of catheter-associated infection in hemodialysis patients: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of using Cloxacillin as an "Antibiotic Lock Solution" versus placebo on prevention of catheter-associated infection in hemodialysis patients

Design

This is a single-blind randomized clinical trial, phase II, in which 124 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible hemodialysis patients who will refer to Shahid Beheshti Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years Hemodialysis

Exclusion criteria: Using immunosuppressive drugs

Intervention groups

Intervention group: Injection of 100 mg/dl Cloxacillin and 1000 IU/ml heparin intra-catheter in every dialysis for 4 weeks
Control group: Injection of 100 mg normal saline and 1000 IU/ml heparin intra-catheter in every dialysis for 4 weeks

Main outcome variables

Primary outcome: Assessing the catheter-associated infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N272**

Registration date: **2019-04-30, 1398/02/10**

Registration timing: **prospective**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

Registration date

2019-04-30, 1398/02/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using Cloxacillin as an "Antibiotic Lock Solution" versus placebo on prevention of catheter-associated infection in hemodialysis patients: a single-blind

randomized clinical trial

Public title

Effect of using Cloxacillin as an "Antibiotic Lock Solution" versus placebo on prevention of catheter-associated infection in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 80 years Hemodialysis

Exclusion criteria:

Using immunosuppressive drugs

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. Thus, the trial will be run as single-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number

IR.UMSHA.REC.1397.484

Health conditions studied

1

Description of health condition studied

Catheter-associated infection

ICD-10 code

T80.21

ICD-10 code description

Infection due to central venous catheter

Primary outcomes

1

Description

Assessing the catheter-associated infection

Timepoint

Every week for 4 weeks

Method of measurement

Through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 100 mg/dl Cloxacillin and 1000 IU/ml heparin intra-catheter in every dialysis for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Injection of 100 mg normal saline and 1000 IU/ml heparin intra-catheter in every dialysis for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan City

Full name of responsible person

Ranyar Abdi

Street address

Shahid Beheshti Hospital, Eram Ave.

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ranyarabdi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Ranyar Abdi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahmoof Gholiaf

Position

Nephrologist

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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