Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Mupirocin Ointment and Chlorhexidine Gluconate Versus Normal Saline in the Prevention of Central Catheter Dialysis-Related Infections

Protocol summary

Study aim

The aim of this study was to determine the effect of Mupirocin Ointment and Chlorhexidine Gluconate Versus Normal Saline in the Prevention of Central Catheter Dialysis-Related Infections

Design

This study is a phase III randomized controlled trial involving 120 patients who will be allocated to three groups—two intervention groups and one control group—through randomization. In the control group, participants will receive normal saline. The two intervention groups will include one group receiving mupirocin and another receiving chlorhexidine, both of which will be applied to the site intended for dressing after each dialysis session before the dressing is placed. The incidence of infection associated with central venous catheterization will be assessed at intervals during the second, third, fourth, fifth, and sixth months.

Settings and conduct

This study is a randomized clinical trial involving a sample of 120 dialysis patients utilizing central catheters at educational hospitals affiliated with Qazvin University of Medical Sciences. These individuals are patients referred to the dialysis unit of the hospital. After each patient visit for dialysis, the trained nurse will administer the medication prior to dressing, depending on whether the patient is in the intervention or control group. The patient, the treating physician, and the individual conducting the analysis are all unaware of the type of intervention, ensuring a blind study design.

Participants/Inclusion and exclusion criteria

inclusion criteria: The patients who require a central venous catheter for dialysis Exclusion criteria: Patients who use a temporary central venous catheter.

Intervention groups

In the intervention group, one group will receive a 2% mupirocin ointment, while another group will receive a 2% chlorhexidine solution in 70% alcohol

Main outcome variables

Infection Caused by the Use of Central Venous Catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241118063765N1**
Registration date: **2025-03-17, 1403/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-17, 1403/12/27**
Update count: **0**

Registration date

2025-03-17, 1403/12/27

Registrant information

Name

Amin Karampour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3333 6001

Email address

amin.karampour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-08, 1403/11/20

Expected recruitment end date

2025-12-11, 1404/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Mupirocin Ointment and Chlorhexidine Gluconate Versus Normal Saline in the Prevention of Central Catheter Dialysis-Related Infections

Public title
Comparative Evaluation of the Effects of Mupirocin Ointment and Chlorhexidine Versus Normal Saline in the Prevention of Dialysis-Related Infections

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent obtained Patients aged 18 years and older Patients on dialysis with a central venous catheter Ability and willingness to participate in the study and adhere to treatment protocols

Exclusion criteria:
Acute or chronic medical conditions that, in the opinion of the Principal Investigator (PI), may interfere with the assessment of the efficacy and/or safety of the study drug Patients who have not received antibiotic treatment for a proven catheter infection in the past month Patients who have not been treated with mupirocin or chlorhexidine in the past month Patients with a history of previous severe allergic reactions or known drug allergies to any of the study treatments Patients with a fistula or a temporary catheter (Shaldon catheter) Patients undergoing routine dialysis for end-stage renal disease (ESRD) who have been hospitalized for any reason

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals were assigned to study groups using balanced block randomization methods with a block size of six. A random sequence was generated using online random generator websites

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin university of medical science

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blvd.

City
Qazvin

Province
Qazvin

Postal code
34417431874

Approval date
2025-01-01, 1403/10/12

Ethics committee reference number
IR.QUMS.REC.1403.394

Health conditions studied

1

Description of health condition studied
Central Catheter Dialysis-Related Infections

ICD-10 code
T82.7

ICD-10 code description
Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

Primary outcomes

1

Description
The rate of central venous catheter infection in dialysis patients

Timepoint
Measurement of infection rate in the second week, third week, fourth week, second month, third month, fourth month, fifth month, and sixth month

Method of measurement
Positive blood culture results and/or fever above 38 degrees Celsius, or hypothermia below 36.5 degrees Celsius during dialysis, and/or cellulitis (swelling, warmth, redness, or purulent discharge around the central catheter)

Secondary outcomes

1

Description
Determining Length of Hospital Stay Due to Central Venous Catheter Infection in Three Groups

Timepoint
Second week, third week, fourth week, second month,

third month, fourth month

Method of measurement

Patient Record

2

Description

Determining Medication Consumption Behavior in Intervention and Control Groups

Timepoint

Checklist

Method of measurement

Second week, third week, fourth week, second month, third month, fourth month

3

Description

The determination of changes in depression in two groups: intervention and control

Timepoint

Second week, third week, fourth week, second month, third month, fourth month

Method of measurement

Patient Health Questionnaire-2 (PHQ-2)

4

Description

The determination of changes in anxiety in two groups: intervention and control

Timepoint

Second week, third week, fourth week, second month, third month, fourth month

Method of measurement

Generalized Anxiety Disorder 2-item (GAD-2)

Intervention groups

1

Description

Intervention group: In this group, 2% chlorhexidine in 70% alcohol will be administered to individuals. Following each dialysis session, prior to catheter insertion, this solution will be applied by the nurse to the patient.

Category

Prevention

2

Description

Intervention group: In this group, mupirocin will be administered to individuals. Following each dialysis session, prior to catheter insertion, this medication will be administered by the nurse to the patient.

Category

Prevention

3

Description

Control group: Individuals in this group will receive normal saline. Following each dialysis session, prior to catheter insertion, this solution will be administered by the nurse to the patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Amin Krampour

Street address

Qazvin University of Medical Sciences.Bahonar Blvd,Qazvin,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Hasan Taherahmadi

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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

Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Amin
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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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
IPD collected for the primary outcome measure only
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
This only available for people working in academic institutions or people working in businesses can also apply to receive it.
Under which criteria data/document could be used
Researchers requiring access must submit formal requests outlining their intended use of the data, which will be reviewed by a data access committee or an institutional review board.
From where data/document is obtainable
Individuals can submit their formal requests to the following email address: “amin.karampour@yahoo.com”.
What processes are involved for a request to access data/document

The process for requesting access to data or documents involves several key steps that require careful attention and adherence to established protocols. Initially, the applicant must prepare a formal request outlining the purpose of the data access, the specific information needed, and its intended use, which may take 1-2 weeks. Following submission, the request undergoes an initial review by the data access committee or institutional review board (IRB), lasting 1-3 weeks, before a thorough evaluation is conducted, which can take an additional 2-4 weeks. The applicant is then notified of the decision, typically within a week.

Comments