

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of Mentha piperita gel dressing for the prevention of phlebitis and local colonization in patients undergoing hemodialysis with temporary central venous catheter

Protocol summary

Study aim

To assess The effect of Mentha piperita gel dressing for the prevention of phlebitis and local colonization in patients undergoing hemodialysis with temporary central venous catheter

Design

Double-blind randomized controlled trial, non-Inferiority, with a parallel group design, on 60 patients, randomized using random sequences generated by the randomization site and numbered in sealed envelopes.

Settings and conduct

This study is a randomized clinical trial on 60 patients undergoing hemodialysis with a temporary central venous catheter in the nephrology ward of Imam Reza Hospital. Patients are randomly divided into two groups of chlorhexidine-impregnated dressing and Mentha piperita and are homogeneous in terms of diabetes in the two groups. These gels are in two similar tube A and B with the same color, smell and appearance. After 24 hours of catheter placement, the control group dressing was impregnated with chlorhexidine gel and the intervention group was impregnated with Mentha piperita gel. These dressings were impregnated with gel twice daily for maximum 14 days and the catheter site was examined daily with Iranian Nurses Association's Inflammatory Criteria. If there was signs of vascular inflammation with score 2 or more, the culture sample will be taken with a sterile swab from the skin around the catheter and sent to the laboratory to be examined for colonization.

Participants/Inclusion and exclusion criteria

Patients undergoing hemodialysis with temporary central venous catheter

Intervention groups

In the intervention group, the central venous catheter dressing was impregnated with Mentha piperita gel 10% and in the control group impregnated with 2%

chlorhexidine gel and used twice daily for a maximum of 14 days.

Main outcome variables

Phlebitis and local colonization at catheter insertion site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220317054324N1**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **prospective**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name

Mohadeseh Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Mentha piperita gel dressing for the prevention of phlebitis and local colonization in patients undergoing hemodialysis with temporary central venous catheter

Public title
The effect of Mentha piperita dressing for the prevention of phlebitis and local colonization

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
The Patient is undergoing hemodialysis due to acute or chronic renal failure The patient has a temporary central venous catheter that is inserted into subclavian or jugular vein Age between 18-60 years The Patient may be hospitalized in the ward for at least 3 days Lack of a known immune deficiency disease such as cancer, AIDS Do not take topical antibiotics and anti-inflammatory at catheter insertion site in a recent week No occurrence of phlebitis at the first change of dressing Lack of sensitivity to the gel in the forearm test
Exclusion criteria:
Systemic and local infection at the catheter insertion site Do not use or can not use the gel for any reason

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomized, controlled, double-blind parallel group trial, 60 patients are randomly divided into intervention and control groups. For simple random allocation, two sequences produced by the randomization site are used, one of which is for random allocation of patients with diabetes and the other is related to the allocation of other patients. in this way, After the available sampling, if the patient has diabetes, the allocation of these patients will be done by a random sequence of patients with diabetes to homogenize the distribution of these patients between the two groups. These two sequences will be placed separately in two different boxes. Each sequences inside the box will be numbered A and B in the sealed envelopes. Mentha

piperita (peppermint) and chlorhexidine gels prepare in two similar tubes with the same color and smell and distinguishe from each other only with A and B. Only a pharmacist is aware of type of gels. patients and relatives are not aware of the type of gel, as well as outcome assessor.

Blinding (investigator's opinion)

Double blinded

Blinding description

The naming of tubes to A and B will be carried out by the pharmacologist assistant in the laboratory of the Faculty of Iranian and complementary medicine of Mashhad University of Medical Sciences and only the pharmacologist is aware of the type of gel. Mentha piperita and chlorhexidine gels prepare in two similar tubes with the same color and smell and distinguishe from each other only with A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of School of Nursing & Midwifery Mashhad University of Medical Sciences

Street address

Faculty of Nursing & Midwifery, Ebne Sina Street, doctora Cross, Daneshgah Ave, Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.003

Health conditions studied

1

Description of health condition studied

Renal failure

ICD-10 code

(N17-N19)

ICD-10 code description

renal failure

Primary outcomes

1

Description

phlebitis

Timepoint

Before the start of the intervention, daily up to maximum 14 days after the intervention

Method of measurement

Iranian Nurses Association's Inflammatory Criteria

Secondary outcomes

1

Description

Local colonization at catheter insertion site

Timepoint

Once If there was signs of vascular inflammation (phlebitis) with score 2 or more

Method of measurement

Blood agar culture and sending samples to Microbiology Laboratory

Intervention groups

1

Description

Intervention group: Mentha piperita extract gel will be used in the intervention group. The researcher will prepare this gel based on carbapol in the laboratory of the Faculty of Iranian and Complementary Medicine of Mashhad University of Medical Sciences under the supervision of a pharmacologist. Mentha piperita is purchased from centers approved by the Faculty of Iranian and Complementary Medicine. Mentha piperita is soaked in a ratio of one to three in hydroalcoholic solvent (30% water and 70% alcohol). After 48 hours, the liquid extract is filtered and the solvent is removed to finally obtain a solid plant extract. Standardization of mint extract is done and then this extract will be prepared in 10% gel base and packed in a tube. For 24 hours after catheter placement, the researcher will change the catheter dressing daily in the morning and then disinfect it with betadine and wash the betadine with normal saline from the wound and apply the gel within a radius of 2.5. After 12 hours, the dressing is opened and the area is impregnated with gel and the same dressing is placed on the site. The researcher, in coordination with the staff, will ensure the use of the gel by face-to-face control or telephone reminders. These dressings are impregnated with gel twice a day for a maximum of 14 days and the catheter site is examined daily with Iranian Nurses Association's Inflammatory Criteria.

Category

Prevention

2

Description

Control group: In this group, 2% chlorhexidine gel is prepared and used. The use of the gel and the evaluation of the catheter entry site for phlebitis and local colonization will be performed in the same way as the intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational, Research and Therapeutic Hospital

Full name of responsible person

Seyed Reza Mazlom

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Emam Reza Hospital, Emam Reza Sq, Ebne Sina St, Mashhad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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

After determining the results, the information will be provided to the Vice Chancellor of Mashhad University of Medical Sciences for implementation in affiliated hospitals and also transferred to the Ministry of Health. Also, some data will be published in scientific journals as the main results of the research within 6 months.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researches who are researching in this field (complementary and Alternative Medicine)

Under which criteria data/document could be used

Analysis of main variables

From where data/document is obtainable

Researcher email

What processes are involved for a request to access

data/document

The data will be provided to the applicants after 1 month.

Comments