

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of aloe vera gel and chlorhexidine gluconate solution 2 % on the prevention of phlebitis caused by peripheral vein catheters in patients admitted to the cardiac intensive care units

Protocol summary

Study aim

Determining and comparing the effect of aloe vera gel and 2% chlorhexidine gluconate solution on the prevention of phlebitis caused by peripheral vein catheters, in patients admitted to Amirul Mominin Hospital (AS) in Zabul city in 2023

Design

Participants are randomly assigned to three test groups using 2% chlorhexidine gluconate solution and aloe vera gel and the control group.

Settings and conduct

This research is a clinical trial study that will be conducted on patients hospitalized in the special care units of Amir al-Mominin Hospital. The participants will be randomly assigned to three test groups.

Participants/Inclusion and exclusion criteria

1. Voluntary participation in the study 2. Age 20 to 70 years 3. Having a healthy upper limb 4. Absence of phlebitis at the site before catheter placement 5. Not taking anticoagulants 6. No history of skin diseases, acute and chronic infection, severe anemia, glaucoma, hypotension (systolic pressure less than 100 mm Hg) 7. Lack of immune system defects 8. No chemotherapy 9. Lack of intravenous nutrition

Intervention groups

After washing the hands for 30 seconds with soap and water and wearing non-sterile gloves, disinfection in the first group is done first with 70% ethyl alcohol, and after drying and entering the venous catheter, then with angioket adhesive that is embedded in the part Its upper part is fixed with half a cc of 2% chlorhexidine gluconate solution, and in the second group, the catheter insertion site is first disinfected with 70% ethyl alcohol, and then after the angioket is inserted, the angioket adhesive pad is soaked with It is aloe vera gel.

Main outcome variables

Reducing phlebitis, hospital costs, increasing patient

satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108059996N1**

Registration date: **2023-12-05, 1402/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-05, 1402/09/14**

Update count: **0**

Registration date

2023-12-05, 1402/09/14

Registrant information

Name

Mahdiyeh Haratinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3223 6156

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-18, 1402/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aloe vera gel and chlorhexidine gluconate solution 2 % on the prevention of phlebitis caused by peripheral vein catheters in patients admitted to the cardiac intensive care units

Public title

Comparison of the effect of aloe vera gel and chlorhexidine gluconate solution 2 % on the prevention of phlebitis caused by peripheral vein catheters in patients admitted to the cardiac intensive care units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Voluntary participation in the study
Age 20 to 70 years
Having a healthy upper limb
Absence of phlebitis at the site before catheter placement
Not taking anticoagulants
No history of skin diseases, acute and chronic infection, severe anemia, glaucoma, hypotension (systolic pressure less than 100 mm Hg)
Lack of immune system defects
No chemotherapy
Lack of intravenous nutrition

Exclusion criteria:

Discharge from the hospital three days before the start of the intervention
Unwillingness to continue cooperation
Rupture or removal of the catheter before 72 hours
pregnancy
Sickness of the patient for any reason
Having diabetes
Simultaneous use of two or more antibiotics
Vasculitis and vascular involvement

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, first, a list of patients who meet the research inclusion criteria will be prepared, and then the first person will be selected in the first intervention group, the second person will be in the third intervention group, and the third person will be selected in the random allocation method. A control will be placed and this work will continue until all research samples are placed in one of the two intervention or control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabol University of Medical Sciences

Street address

Shilat Square - Motahari Street - Motahari corner 2

City

زابل

Province

Sistan-va-Balouchestan

Postal code

9861664656

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.ZBMU.REC.1401.152

Health conditions studied

1

Description of health condition studied

phlebitis

ICD-10 code

I80

ICD-10 code description

Phlebitis and thrombophlebitis

Primary outcomes

1

Description

phlebitis

Timepoint

Every 12 hours

Method of measurement

Phlebitis checklist

Secondary outcomes

1

Description

Phlebitis

Timepoint

Every 12 hours

Method of measurement

Phlebitis checklist

Intervention groups

1**Description**

IntervenAfter washing your hands for 30 seconds with soap and water and wearing non-sterile gloves to protect yourself, preparing the intravenous fluid and serum set in a sterile way and choosing the appropriate vein, disinfection in the first group is done with 70% ethyl alcohol. And after the venous catheter is dried and inserted, then the upper part of the catheter insertion site is fixed with angioket adhesive, which has a pad embedded in its upper part, dipped in half a cc of 2% chlorhexidine gluconate solution.

Category

Prevention

2**Description**

In the second group, the catheter insertion site is first disinfected with 70% ethyl alcohol, then the selected area, after drying and entering the venous catheter, is then smeared with half a cc of aloe vera gel with angioket adhesive, which has a pad embedded in its upper part. The upper part of the catheter entry point is fixed.

Category

Prevention

3**Description**

In the control group, only the insertion site of the catheter is disinfected with 70% ethyl alcohol and the catheter is fixed using glue in a standard way. The date, time and name of the researcher are recorded. Every 12 hours to 72 hours, the site is checked and recorded for signs and degree of phlebitis. The serum set in 3 groups is changed every 24 hours and the duration of maintenance of the venous catheter is 72 hours.

Category

Prevention

Recruitment centers1**Recruitment center****Name of recruitment center**

Amir al-Mominin Ali (AS) Zabul Hospital

Full name of responsible person

Dr. Mohammad Ayman Abilinejad

Street address

3 km of Zabul-Zahedan road

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5434211294

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Email**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Zabol University of Medical Sciences

Full name of responsible person

Dr. Khadijah Rezaei Kikhaei

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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

Zabol University of Medical Sciences

Proportion provided by this source

10

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**

Zabol University of Medical Sciences

Full name of responsible person

Mahdieh Herati Nesab

Position

Special care master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Mahin Naderi Far

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available