

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the transparent dressing and impregnated dressing with chlorhexidine 2% on the colonization at the site of central venous catheter in patients hospitalized in intensive care unit

Protocol summary

Study aim

Comparison of the transparent with gauze dressing impregnated with chlorhexidine 2% on the colonization at the site of central venous catheter in patients hospitalized to the intensive care unit

Design

A randomized, controlled trial. The block method was used for randomization.

Settings and conduct

This study will be performed in Shahid Chamran Hospital in Boroujerd and on patients hospitalized to the intensive care unit. Samples are randomly divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 60 years, lack of known infection in any part of the body. Exclusion criteria: Lack of known infection in any part of the body.

Intervention groups

Intervention group: For patients in the intervention group, a transparent dressing impregnated with 2% chlorhexidine solution produced by Morvabon company will be used. The dressing is transparent, impermeable to moisture and made of polyurethane with dimensions of 10. 10 cm. The transparent dressing will be changed every 4 days. Control group: In the control group, sterile gauze with dimensions of 10 × 10 cm impregnated with 2 ml of chlorhexidine solution will be used in similar conditions. The gauze dressing will be changed every day.

Main outcome variables

Microbial colonization at the site of the central venous catheter.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210408050900N1**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Majid Goodarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4231 3904

Email address

m.goudarzi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the transparent dressing and impregnated dressing with chlorhexidine 2% on the colonization at the

site of central venous catheter in patients hospitalized in intensive care unit

Public title

The effect of chlorhexidine dressing on the colonization at the site of central venous catheter

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 60 years Lack of known infection in any part of the body

Exclusion criteria:

Dissatisfaction of the patient or family to participation in the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

To generate the random sequence, permutation block randomization will be used. At first, 6 blocks will be constructed as "ABBA, BAAB, AABB, BBAA, BABA, ABAB", then these blocks are arranged using a random number table, and individuals will be assigned to two groups according to A and B letters.

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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2021-04-28, 1400/02/08

Ethics committee reference number

IR.ARAKMU.REC.1400.015

Health conditions studied

1

Description of health condition studied

Microbial colonization of the central venous catheter entry site

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Number of bacteria at the site of central venous catheter

Timepoint

At the beginning of the study (before the intervention) and 4 days after dressing

Method of measurement

Sabroud Dextrose Agar culture medium

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients in the intervention group, a transparent dressing impregnated with 2% chlorhexidine solution produced by Morvabon company will be used. The dressing is transparent, impermeable to moisture and made of polyurethane with dimensions of 10. 10 cm. The dressing will be changed every 4 days.

Category

Prevention

2

Description

Control group: In the control group, sterile gauze with dimensions of 10 × 10 cm impregnated with 2 ml of chlorhexidine solution will be used in similar conditions. The gauze dressing will be changed every day.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran hospital

Full name of responsible person

Afsane Amam Dost

Street address

Daneshgah St., Fatemi St.

City

Boroujerd

Province

Lorestan

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6813833946

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Majid Goudarzi

Position

Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It is provided unrecognizably at the request of individuals.

When the data will become available and for how long

The access period will start after the results are printed.

To whom data/document is available

Researchers at other Universities are allowed access.

Under which criteria data/document could be used

Documentation is provided in order to know how the work is done and to critique it.

From where data/document is obtainable

Majid Goudarzi majidgoodarzi1365@gmail.com

What processes are involved for a request to access data/document

After stating the purpose of accessing the information, the requested items will be sent via email.

Comments