

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of daily 2% chlorhexidine bathing, on colonization of the skin of patients admitted to Khatam's hospital ICU of the Zahedan University of Medical Sciences in 2017.

Protocol summary

Summary

The present research is random study without control by placebo. The statistical population includes all patients admitted to the intensive care unit of Khatam Hospital, affiliated with Zahedan University of Medical Sciences, in 2017. In these patients, patients with multiple trauma, aged 20-60 who were hospitalized in the ICU for at least 48 hours were selected as the sample. The exclusion criteria were affliction with infectious diseases or diabetes, pregnancy (for women), and discharge or transfer to another ward before 48 hours. Sample size: Based on previous studies and considering a statistical power of 90% at a confidence level of 95%, the sample size for each of the experimental groups was determined to be 35. To increase the level of confidence and compensate for possible loss of samples, 40 subjects were assigned to each group. Intervention: In the control group, sampling will be done using a sterile swab from areas of the armpits, groin, and neck folds on arrival at the hospital and 48 hours after hospitalization without any intervention. Sampling of the same body areas in the intervention group will be conducted with the same method on arrival at the hospital and 48 hours after hospitalization and daily 2% chlorhexidine bath. For bathing, the entire body of patients, except their face, should be treated with a pad containing 2% chlorhexidine solution. Samples will be cultured by the fellow researcher and, 24 hours after incubation, the number of colonies will be counted. Then, samples will be cultured again for determining the type of microorganisms and conduction of antibiotic sensitivity test. Finally, the results of two groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030932293N1**

Registration date: **2017-03-21, 1396/01/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

Name

Hamed Sarani

Name of organization / entity

Zahedan University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2481

Email address

sarani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of daily 2% chlorhexidine bathing, on colonization of the skin of patients admitted to Khatam's hospital ICU of the Zahedan University of Medical Sciences in 2017.

Public title

Chlorhexidine effect on skin colonization

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: In these patients, patients with multiple trauma, aged 20-60 who were hospitalized in the ICU for at least 48 hours were selected as the sample. Exclusion criteria: The exclusion criteria were affliction with infectious diseases or diabetes, pregnancy (for women), and discharge or transfer to another ward before 48 hours.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Zahedan University of Medical Sciences

Street address

Zahedan University Medical Sciences, Hesabi Sq,
University Street, Zahedan

City

Zahedan

Postal code

9816913396

Approval date

2017-01-01, 1395/10/12

Ethics committee reference number

IR.ZAUMS.REC.1395. 247

Health conditions studied**1****Description of health condition studied**

nosocomial infection

ICD-10 code

B99

ICD-10 code description

Other and unspecified infectious diseases

Primary outcomes**1****Description**

colonies number

Timepoint

First and third days of hospitalization

Method of measurement

culture

2**Description**

type of micro-organisms

Timepoint

First and third days of hospitalization

Method of measurement

culture

3**Description**

Drug resistance

Timepoint

First and third days of hospitalization

Method of measurement

Antibiotic SensitivityTest

Secondary outcomes**1****Description**

duration of hospitalization

Timepoint

-

Method of measurement

days

Intervention groups**1****Description**

In the control group, sampling will be done using a sterile swab from areas of the armpits, groin, and neck folds on arrival at the hospital and 48 hours after hospitalization without any intervention.

Category

N/A

2

Description

Sampling of the same body areas in the intervention group will be conducted with the same method on arrival at the hospital and 48 hours after hospitalization and daily 2% chlorhexidine bath. For bathing, the entire body of patients, except their face, should be treated with a pad containing 2% chlorhexidine solution. Samples will be cultured by the fellow researcher and, 24 hours after incubation, the number of colonies will be counted. Then, samples will be cultured again for determining the type of microorganisms and conduction of antibiotic sensitivity test. Finally, the results of two groups will be compared with each other.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatm-al-anbia hospital affiliated with the Zahedan University of Medical Sciences

Full name of responsible person

Hamed sarani

Street address

Nursing and Midwifery Department, Zahedan University of Medical Sciences, Dr Hesabi Sq, University Street, Zahedan, Iran

City

Zhedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hamed sarani

Street address

Zahedan University of Medical Sciences, Dr Hesabi square, University Street

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hamed sarani

Position

Masters

Other areas of specialty/work

Street address

Nursing and Midwifery Department, Zahedan Medical Sciences University, Hesabi Sq, university street, Zahedan, Iran.

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Soleiman bidar

Position

Student

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Postal code**Phone**

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Fax**Email**

s.bidar16@yahoo.coms.bidar62@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty