

# 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.

#### City

Zahedan

#### Postal code

9816653948

#### Phone

+54 33442481

#### Fax

+54 33442481

#### Email

sarani@zaums.ac.ir

#### Web page address

www.zaums.ac.ir

## Person responsible for scientific 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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#### Email

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www.zaums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Soleiman bidar

**Position**

Student

**Other areas of specialty/work****Street address**

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Mahabad, West Azarbaijan, Iran

**City**

Mahabad

**Postal code****Phone**

+98 44 4235 1647

**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*