

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the effects of Chlorhexidine solution, Alcohol and Alcohol-Chlorhexidine on complications of Peripheral venous catheter (phlebitis and local infections)

#### Protocol summary

##### Summary

The purpose of this study was to compare the effect of using disinfectant solutions before injection (alcohol, chlorhexidine and alcohol+chlorhexidine) on the complications of intravenous catheterization in patients. This study was conducted on 147 patients who were eligible to enter the study by having inclusion criteria such as 18-60 years old age, healthy upper limb, lack of other underlying conditions like cancer, etc. Patients were randomly divided into three groups of 49 people. Before the intervention, they were provided with some explanations for the study and the written consent was obtained from them. The catheter injection site was checked for phlebitis every 12 hours. Nursing Association's phlebitis scale was used to evaluate phlebitis, which a score more than 2 was considered as phlebitis according to the scale. At the time of the catheter exit, for any reason, the tip of the catheter in a sterilized way with no contact to the skin surface was separated with a sterile scissor and sent to the laboratory for a microbiological examination. Angiocatheter tip culture was prepared in a semi-quantitative manner in an agar medium. The number of colonies emerging in the culture medium was counted after 48 hours. If their number is more than 15, the catheter is considered infectious. In this study, the patient and phlebitis and laboratory assessor were unaware and blind to the disinfectant substance before cannulation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017050532293N2**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-29, 1396/08/07

##### 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

Vice Chancellor for research of Zahedan University of Medical Sciences .Dr Noormohammad Bakhshani

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-03-22, 1397/01/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of Chlorhexidine solution, Alcohol and Alcohol-Chlorhexidine on complications of Peripheral venous catheter (phlebitis and local infections)

##### Public title

Effects of Chlorhexidine solution, Alcohol and Alcohol-Chlorhexidine on complications of Peripheral venous catheter

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## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; At least for 72 hours need to have an intravenous catheter; Does not have underlying diseases, such as leukemia, immune deficiency, diabetes and dermatitis; Do not sensitive to adhesive or injection; No blood transfusion; Not been in hemodialysis; Have a healthy upper limbs and healthy upper extremity skin with natural color; have Systolic pressure above 90 mm Hg. Exclusion criteria: Accidents that lead to early replacement of the catheter; injecting a drug solution that is effective on duration of catheter replacement as hypertonic solutions (manitol, dextrose 50%, dextrose20%, dextrose saline, etc.)

## Age

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

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **147**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple 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 Zahedan University of Medical Sciences

##### Street address

Zahedan University of Medical Sciences, Dr Hesabi Sq, University Street, Zahedan, Iran

##### City

Zahedan

##### Postal code

9816653948

##### Approval date

2017-05-28, 1396/03/07

##### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Local infection

#### ICD-10 code

L08

#### ICD-10 code description

Other local infections of skin and subcutaneous tissue

### 2

#### Description of health condition studied

Phlebitis and thrombophlebitis

#### ICD-10 code

I80.9

#### ICD-10 code description

Phlebitis and thrombophlebitis of unspecified site

## Primary outcomes

### 1

#### Description

Phlebitis

#### Timepoint

12 Hour after venous catheterization;24Hour after venous catheterization;36Hour after venous catheterization;48;60Hour after venous catheterization

#### Method of measurement

Phlebitis Grading Scale

## Secondary outcomes

### 1

#### Description

Local catheter site infection

#### Timepoint

After removing the IV catheter

#### Method of measurement

Based on the test results and the number of colonies grown culture from the catheter tip

## Intervention groups

### 1

#### Description

The catheter injection site was initially disinfected by application of alcohol with the brand of "Manicol" which is a product of "Sina Fariman Chemical Industry" and then the cannulation was conducted. As well as, the site of the catheter was fixed with sterile dressing gauze and anti-allergic band aid.

#### Category

Prevention

## 2

### Description

The catheter injection site was initially disinfected by application of Chlorhexidine with the brand of "Epimax U" which is a product of "Emad Pharmaceutical company" and then the cannulation was conducted. As well as, the site of the catheter was fixed with sterile dressing gauze and anti-allergic band aid.

### Category

Prevention

## 3

### Description

The catheter injection site was initially disinfected by application of alcohol-Chlorhexidine with the brand of "Epimax" which is a product of "Emad Pharmaceutical company" and then the cannulation was conducted. As well as, the site of the catheter was fixed with sterile dressing gauze and anti-allergic band aid.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam al anbia hospital

##### Full name of responsible person

Hamed sarani

##### Street address

##### City

Zahedan

### 2

#### Recruitment center

##### Name of recruitment center

Ali ebn abitaleb hospital

##### Full name of responsible person

Hamed sarani

##### Street address

##### City

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Zahedan University of Medical Sciences

##### Full name of responsible person

Dr. Noormohammad Bakhshani

##### Street address

Zahedan University of Medical Sciences, Dr Hesabi Sq

##### City

Zahedan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for research of 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

Master

#### Other areas of specialty/work

#### Street address

Mashahir Sq. Nursing and Midwifery Department

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9816653948

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Enayatollah Safarzai

**Position**

Master student of Medical- Surgical Nursing,

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00

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## 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*