Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Siences

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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

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

IR.ZAUMS.REC.1396. 37

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
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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
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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
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
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Hamed Sarani
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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