

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of the Effect of Chlorhexidine Gluconate 2% with Transdermal Nitroglycerine Ointment 2% in Prevention of Phlebitis Due to Catheterization

Protocol summary

Summary

Objectives: The purpose of this study was a randomized controlled trial, This study is The effect of 2% chlorhexidine solution and 2% Nitroglycerin Ointment after disinfection with 70% ethanol to prevent phlebitis at the catheter in the hospital Yahya Nejad Babol.

Design: The study was a randomized clinical trial on 100 patients in the two groups in heart and cardiac care unit. Means of data collection for this study included demographic and medical questionnaire developed by the researcher and It is the list of degrees of phlebitis. Medical questionnaire for demographic data included age, sex, diagnosis, type of underlying disease, parenteral medications, medical group, signs of phlebitis and catheter insertion . Phlebitis degrees based on symptoms such as pain, warmth, the redness and swelling, And it was checked every 12 hours. Participation in the study will assess eligibility. Non-random sampling method is available. patients were randomly placed in two groups. These numbers were based on a 2% Chlorhexidine and 2% Nitroglycerin Ointment .

Interventions: All sampling procedures and catheter insertion and injection site skin disinfection to prevent bias by the investigator to be done this way: A) Prepare the equipment b) Wash hands with soap and water for 30 seconds c) wear sterile gloves to protect themselves d) preparation of sterile intravenous fluid and serum sets) chosen vein appropriate) aseptic catheter insertion site with chlorhexidine 2% in the first group and the second group with 70% ethanol g) drying the choice c) A peripheral venous catheter insertion) Nitroglycerin Ointment 2% in the group i) fixing the catheter to the standard method of using glue) records the date, time and name of the Investigator. 5 × 5 on sterile gauze dressing is placed and fixed with adhesive tape . If the error occurs more than twice the catheter insertion site is chosen for the injection. Every 12 hours for signs of

phlebitis and temperature are controlled in groups of 2% Nitroglycerin ointment once again just after cleaning and dressing ointment is used on a stand. Participants including major eligibility criteria: Inclusion criteria including: age over 20 years; having ordered intravenous catheterization, the patient's consent, the patient having to be alert and cooperative. Exclusion criteria including; immune deficiency and anemia in patients receiving immune-lowering drugs, and cardiovascular disease, skin disease, patients receiving hypertonic substances, diabetes, dialysis, and patients with underlying diseases such as leukemia, kidney, lung Chronic liver disease and receiving medications such as antibiotics, amiodarone, ranitidine, diazepam, phenytoin and corticosteroids, pregnant women, nursing mothers, people with headaches, glaucoma or increased intracranial pressure, hypotension (systolic pressure less than 100 mm Hg), hypertension (pressure greater than 180 mm Hg) and a blood transfusion is administered. The main outcome variables: the prevention of phlebitis, infection control

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304077494N5**
Registration date: **2013-09-04, 1392/06/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-04, 1392/06/13

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country	Iran (Islamic Republic of)	Randomization (investigator's opinion)	Randomized
Phone	+98 11 3336 7551	Randomization description	
Email address	mbagheri@mazums.ac.ir	Blinding (investigator's opinion)	Not blinded
Recruitment status		Blinding description	
Recruitment complete		Placebo	Not used
Funding source	Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari .	Assignment	Parallel
Expected recruitment start date	2013-04-04, 1392/01/15	Other design features	
Expected recruitment end date	2013-07-01, 1392/04/10	Secondary Ids	empty
Actual recruitment start date	empty	Ethics committees	
Actual recruitment end date	empty	<u>1</u>	
Trial completion date	empty	Ethics committee	
Scientific title	The Comparison of the Effect of Chlorhexidine Gluconate 2% with Transdermal Nitroglycerine Ointment 2% in Prevention of Phlebitis Due to Catheterization	Name of ethics committee	Ethical committee of Mazandaran University of Medical Science
Public title	The Comparison of the Effect of Chlorhexidine Gluconate 2% with Transdermal Nitroglycerine Ointment 2% in Prevention of Phlebitis Due to Catheterization.	Street address	Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.
Purpose	Prevention	City	Sari
Inclusion/Exclusion criteria	Inclusion criteria included age over 20 years; having ordered intravenous catheterization; the patient's consent; the patient having to be alert and cooperative. Exclusion criteria included patients with immune deficiency and anemia; drugs recipient safety; and cardiovascular disease; skin disease; patients receiving hypertonic substances; diabetes;; dialysis; and patients with underlying diseases such as leukemia, kidney disease, chronic lung and liver; and receiving medications such as antibiotics, amiodarone, ranitidine, diazepam, phenytoin and corticosteroids; pregnant women; nursing mothers; people with headaches; glaucoma or increased intracranial pressure; hypotension (systolic pressure less than 100 mm Hg); hypertension (pressure more than 180 mm Hg); and a blood transfusion is administered.	Postal code	
Age	From 20 years old to 65 years old	Approval date	2013-03-06, 1391/12/16
Gender	Both	Ethics committee reference number	282-91
Phase	2-3	Health conditions studied	
Groups that have been masked	No information	<u>1</u>	
Sample size	Target sample size: 100	Description of health condition studied	phlebitis
		ICD-10 code	I80.8
		ICD-10 code description	Phlebitis and thrombophlebitis of other sites
		Primary outcomes	
		<u>1</u>	
		Description	phlebitis
		Timepoint	Before and during the study - the first to the 3th day of hospitalization
		Method of measurement	checklist
		Secondary outcomes	

1

Description

Prevention of phlebitis

Timepoint

post and every day until the 3th day.

Method of measurement

phlebitis scale

Intervention groups

1

Description

The intervention group Nitroglycerin Ointment, alcohol): After selecting the desired vein and disinfected with 70% Ethanol and paste the catheter was fixed to the skin. The distal portion of the catheter by Nitroglycerin Ointment and dressings are impregnated century . cathter portion was assessed each 12 hour and In the absence of previous phlebitis and clean again with the ointment nitroglycerin ointment and a bandage is applied in the same area.

Category

Treatment - Drugs

2

Description

Intervention group and 2% chlorhexidine solution: This solution contains alcohol, which is 0.5% chlorhexidine solution to disinfect the area as cotton impregnated catheters are used. After selecting a suitable vein, the choice of the vain disinfect with antiseptic solution and then the catheter is fixed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nejad Hospital

Full name of responsible person

Javid Khodadadyan Miri

Street address

Yahya Nejad Hospital. martyr Mostafa Khomeini, the Farhang Cross, Babol.

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Dr Masumeh Bagheri Nesami

Street address

Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.

City

Sari

Grant name

در حال بررسی

Grant code / Reference number

Being investigated

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Science

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

Mazandaran University of Medical Science

Full name of responsible person

Dr Mohamad Ali Heydari Gorj

Position

Phd- faculty

Other areas of specialty/work

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Fax**Email**

anna3043@gmail.com, anna30432003@yahoo.com

Web page address**Person responsible for updating data****Contact****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