Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari .

Expected recruitment start date
2013-04-04, 1392/01/15
Expected recruitment end date
2013-07-01, 1392/04/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
The Comparison of the Effect of Chlorhexidine Gluconate 2% with Transdermal Nitroglycerine Ointment 2% in Prevention of Phlebitis Due to Catheterization.
Purpose
Prevention
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.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**

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
Ethical committee of Mazandaran University of Medical Science
Street address
Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.
City
Sari
Postal code
Approval date
2013-03-06, 1391/12/16
Ethics committee reference number
282-91

Health conditions studied

1

Description of health condition studied
phlebitis
ICD-10 code
I80.8
ICD-10 code description
Phlebitis and thrombophlebitis of other sites

Primary outcomes

1

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

Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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City
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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
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Position
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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