

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The Effect of Intermittent Normal Saline Flush On Patency of Peripheral Venous Catheter and Prevention of Phlebitis and infiltration: a Single-Blind Randomized Controlled Trial

Protocol summary

Summary

Aim: Investigation of the effect of intermittent normal saline flush on patency of peripheral venous catheter and prevention of phlebitis and infiltration in hospitalized patients in Imam Reza Hospital in Tabriz 1393. design and Methods: A a Single-Blind Randomized Controlled Trial was conducted (the researcher who measured phlebitis).At each visit the patients, those who met inclusion criteria consecutively assigned in three groups, using a table of random numbers, Two intervention groups (Group I: n=50, intervention every 8 hours and the second group n=50, intervention every 12 hours), and a control group (n=50) with an allocation ratio of 1: 1: 1. In the first intervention group every 8 hours and in the second intervention group every 12-hours, the intravenous catheter was flushed with 3 ml of normal saline solution for 72 hours (and also before and after every other infusion), and the control group not receiving the intervention according to current routine. Followed by 24-48-72 hours after the first intervention, Catheter complications observed by trained nurses using a structured check list.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062118176N1**

Registration date: **2014-08-30, 1393/06/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-30, 1393/06/08

Registrant information

Name

Morteza Fotowati

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz Nursing & Midwifery Faculty

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intermittent Normal Saline Flush On Patency of Peripheral Venous Catheter and Prevention of Phlebitis and infiltration: a Single-Blind Randomized Controlled Trial

Public title

The effect of saline lock on prevention of phlebitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: adult patients (Older than 18 years old)

admitted to the medical-surgical wards that will hospitalized at least three days after surgery; patients with peripheral intravenous catheter in the upper limb (on the forearm) and patients who were willing to participate. Exclusion criteria: patients who had any underlying blood disorders (eg, hemophilia, diabetes, etc); patients who receiving anticoagulant therapy (heparin, warfarin, Plavix, etc); patients who receiving IV potassium chloride; patients who receiving continuous intravenous fluid therapy; replacement of the catheter for any reason other than phlebitis; discharged or died during the study period; emergency situation that requires immediate medical or nursing interventions, such as cardiopulmonary resuscitation.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Variables such as gender and age, that affecting the incidence of phlebitis based on previous studies were lowered with random allocation of variable. All catheters by one person and in the cephalic vein of the forearm will be fixed with once tried out.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Department of Tabriz University of Medical Sciences

Street address

No 2 Building -3 floor -Deputy Of Research-Tabriz University Of Medical Sciences- Golgasht st-Tabriz

City

Tabriz

Postal code

51665118

Approval date

2014-06-23, 1393/04/02

Ethics committee reference number

9350

Health conditions studied

1

Description of health condition studied

Phlebitis

ICD-10 code

T80.1

ICD-10 code description

Vascular complications following infusion, transfusion and therapeutic injection

Primary outcomes

1

Description

Phlebitis

Timepoint

24-48-72 hours, respectively, after the pre-test

Method of measurement

Visual Analogue Scale phlebitis

Secondary outcomes

1

Description

Infiltration and the patency of the catheter

Timepoint

respectively, 24-48-72 hours after the pre-test

Method of measurement

Observation checklist and visual analogue scale infiltration

Intervention groups

1

Description

In the first intervention group, IV catheter, flushed with 3 ml of normal saline every 8 hours for 72 hours, also before and after of any injection.

Category

Treatment - Drugs

2

Description

In the second intervention group, IV catheter, flushed with 3 ml of normal saline every 12 hours for 72 hours, and also before and after of any injection.

Category

Prevention

3

Description

control group not receiving the intervention according to current hospital routines.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz

Full name of responsible person

Morteza Fotowati

Street address

Imam Reza Hospital, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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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

Research Deputy of Tabriz 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

Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery

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Position

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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