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: 0
Registration date 2014-08-30, 1393/06/08
Registrant information
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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, 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
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City
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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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City
Tabriz
Grant name

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

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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