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
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 7713
Email address
fotowatim@tbzmed.ac.ir

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

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

**Category**
- N/A

**Recruitment centers**

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Imam Reza Hospital, Tabriz</td>
<td>Morteza Fotowati</td>
<td>Imam Reza Hospital, Tabriz</td>
<td>Tabriz</td>
</tr>
</tbody>
</table>

**Sponsors / Funding sources**

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Research Deputy of Tabriz University of Medical Sciences</td>
<td>Dr. Mohammad Reza Rashidi</td>
<td>No 2 Building -3 floor -Deputy Of Research-Tabriz University Of Medical Sciences- Golgashst st-Tabriz</td>
<td>Tabriz</td>
</tr>
</tbody>
</table>

**Person responsible for general inquiries**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery</td>
<td>Morteza Fotowati</td>
<td>Master of Nursing Student</td>
</tr>
</tbody>
</table>

**Person responsible for scientific inquiries**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery</td>
<td>Hadi Hassankhani</td>
<td>Ph.D. in Nursing</td>
</tr>
</tbody>
</table>

**Person responsible for updating data**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences</td>
<td>Morteza Fotowati</td>
<td>Master of Nursing Student</td>
</tr>
</tbody>
</table>

**Grant name**
- Research Deputy of Tabriz University of Medical Sciences

**Grant code / Reference number**
- 1

**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**
- empty

**Type of organization providing the funding**
- empty

**Person responsible for scientific inquiries**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery</td>
<td>Hadi Hassankhani</td>
<td><a href="mailto:fotowati@gmail.com">fotowati@gmail.com</a>; <a href="mailto:fotowati@yahoo.com">fotowati@yahoo.com</a>; <a href="mailto:fotowatim@tbzmed.ac.ir">fotowatim@tbzmed.ac.ir</a></td>
</tr>
</tbody>
</table>

**Person responsible for updating data**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences</td>
<td>Morteza Fotowati</td>
<td><a href="mailto:fotowati@gmail.com">fotowati@gmail.com</a>; <a href="mailto:fotowati@yahoo.com">fotowati@yahoo.com</a>; <a href="mailto:fotowatim@tbzmed.ac.ir">fotowatim@tbzmed.ac.ir</a></td>
</tr>
</tbody>
</table>

**City**
- Tabriz

**Postal code**
- 3417174914

**Phone**
- +98 41 1479 6770

**Fax**
- +98 41 1475 2839

**Email**
- fotowati@gmail.com; fotowati@yahoo.com; fotowatim@tbzmed.ac.ir

**Web page address**
- empty
Phone
+98 41 1479 6770
Fax
Email
fotowati@gmail.com; fotowati@yahoo.com;
fotowatim@tbzmed.ac.ir
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