

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparing the effect of continuous versus pulsative flushing on the phlebitis incidence , patency and longevity of peripheral intra venous catheter in patients admitted to medical and surgical ward of Eesfarayen Hospital

Protocol summary

Study aim

Determine the comparative effect of continuous versus pulsative flushing on the phlebitis incidence, patency and longevity of peripheral intra venous catheter in patients admitted to medical and surgical wards of Eesfarayen Hospital

Design

A clinical trial study of three groups, single blind and randomize assignment.

Settings and conduct

After obtaining Ethics Committee permission and permission from Esfarayn faculty of Medical Sciences and the officials of Imam Khomeini Esfarayn Hospital, first choose sample selection with form then eligible patients were selected using a goal-based sampling method and then explained. The purpose of the research and how it will be done, the patients will receive written consent to participate in the research, and they will be informed that they can be dissuaded from continuing to participate in the research whenever they wish.

Participants/Inclusion and exclusion criteria

The participants of this study are patients admitted to the internal and surgical wards of Imam Khomeini Hospital Esfarayne. inclusion includes patients 18 to 65 years old that hospitalized for at least 96 hours and exclusion criteria including taking an anticoagulant drugs.

Intervention groups

In the first intervention group (pulsative flushing), before injection of the first drug into the intravenous catheter, five milli liter(m.l) of the 0.9% NaCl solution, which Pre-prepared into 5-m.l syringe, put up top of the catheter that had one-way valve. Then, one m.l of the solution is injected into the catheter within one second, then 0.4 seconds is interrupted and again one m.l is injected within one second, this procedure continues until the

evacuate five milliliters 0.9% NaCl solution. Then the patient's drug is injected in accordance with the leaflet or the physician's order. After the drug is finished, if they have another drug, before the second drug is injected, the pulsative Flushing method described above is repeated and then the second drug is injected. These steps will continue until patient medications to be completed . Finally, locking technique performed (one m.l of 0.9% NaCl solution is slowly injected with a two m.l syringe through heparin lock that located at the end of the p.v.c) and the patient's catheter until the next patient's drug is administered remains intact (minimum time is six hours from the last injection). In the second intervention group (pulsative flushing), before injection of the first drug into the intravenous catheter, five milli liter(m.l) of the 0.9% NaCl solution, which Pre-prepared into 5-m.l syringe, put up top of the p.v.c that had one-way valve. Injection will be done within 5 seconds. Then the patient's drug is injected in accordance with the leaflet or the physician's order. After the drug is finished, if they have another drug, before the second drug is injected, the continuous flushing method described above is repeated and then the second drug is injected. finally locking technique performed. In the control group, drugs are injected at a predetermined time.

Main outcome variables

Peripheral catheter phlebitis: The patient score obtains from a phlebitis visual check list. patency of p.v.c : Lack of resistance to drug injection with or without blood return. Longevity of p.v.c : period of time which there is not evidence shows the catheter functional ended or catheter is not prohibited, time will be recorded per hours (maximum time is 96 hours).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020394N4**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Mahbobeh Firooz

Name of organization / entity

Mashhad Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Esfarayen University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of continuous versus pulsative flushing on the phlebitis incidence , patency and longevity of peripheral intra venous catheter in patients admitted to medical and surgical ward of Eesfarayen Hospital

Public title

Comparing the effect of continuous versus pulsative flushing on the phlebitis incidence, patency and longevity of peripheral intra venous catheter

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 65 years old at least 96 hours are hospitalized

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

PASS software

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be a single blind. After giving explanations to the patients about the method of study completely and consent of patients, they fall into one of the three groups of continuous flushing, pulsative flushing and control group that they are not informed about type of group. Next, assigned to the patient a code. numbers: one, four , Seven, ... belong to continuous Flushing , numbers: two, five, eight, ... belong to Flushing group and numbers: three, six, nine, and ... belong to the control group.

Placebo

Not used

Assignment

Single

Other design features

Secondary ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Blvd Tohid Shahr,sabzevar town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2017-01-04, 1395/10/15

Ethics committee reference number

IR.MEDSAB.REC.1395.112

Health conditions studied

1

Description of health condition studied

This study was performed on patients admitted to medical and surgical department of Eesfarayen Hospital

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Phlebitis incidence

Timepoint

Every 12 hours to 4 days

Method of measurement

Visual Infusion Phelebit Scale

2

Description

Catheter patency

Timepoint

Every 12 hours to 4 days

Method of measurement

lack of resistant against injection from peripheral intra venous catheter

3

Description

longevity of peripheral intra venous catheter

Timepoint

Every 12 hours to 4 days

Method of measurement

Maximum catheter longevity in situ is 96 hours

Secondary outcomes

1

Description

phelebitis of peripheral intra venous catheter

Timepoint

Every 12 hours For 4 days

Method of measurement

Visual Infusion Phelebit Scale

2

Description

Catheter patency

Timepoint

Every 12 hours For 4 days

Method of measurement

lack of resistance against of injection

3

Description

Catheter longevity

Timepoint

Every 12 hours For 4 days

Method of measurement

catheter remain in situ for maximum for 96 hours.

Intervention groups

1

Description

Intervention group1: patients admitted to medical and surgical ward; interventions includ: pulsative flushing in time of drug administration, and then check the phlebitis incidence, patency and longevity of peripheral intra venous catheter every 12 hour

Category

Prevention

2

Description

Intervention group2: patients admitted to medical and surgical ward; interventions includ: continuous flushing in time of drug administration, and then check the phlebitis incidence, patency and longevity of peripheral intra venous catheter every 12 hou

Category

Prevention

3

Description

Control group: Patient drugs are injected according to pre determinated time , and every 12 hours to 96 hours, the catheter is controlled by phlebitis and patency.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Esfarāyen

Full name of responsible person

mahbobeh firooz

Street address

Imam Reza Street, Esfarāyen Town

City

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Province

North Khorasan

Postal code

96618-76981

Phone

+98 58 3722 6005

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfarayen University of Medical Sciences

Full name of responsible person

Eshagh Ildarabadi

Street addressImam Reza Street , Faculty of Medical Sciences
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Email

ildarabadi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfarayen University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Faculty of Medical Sciences Esfarāyen

Full name of responsible person

Mahbobeh firooz

Position

Master of Nursing , Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street addressFaculty of Medical Sciences
Esfarāyen,Esfarāyen,North Khorasan**City**

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Full name of responsible person

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Position

MS Nursing , Faculty member

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Position

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Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study report will be published in the form of articles in journals

When the data will become available and for how long

After the publication in the journal

To whom data/document is available

All interested in the subject of the study

Under which criteria data/document could be used

In order to use it in clinical practice

From where data/document is obtainable

Electronic databases

What processes are involved for a request to access data/document

search done by purposful keywords includes:"flushing", "phlebitis", "patency of peripheral catheter"

Comments