

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparing the effects of Flushing and Saline Lock on phlebitis and patency time of peripheral intravenous catheters in patients admitted to the medical department

Protocol summary

Study aim

Determine the effects of Flushing and Saline Lock on phlebitis and patency time of peripheral intravenous catheters in patients admitted to the medical and surgical department of imam khomeini Hospital, Eesfarayen

Design

A randomized controlled clinical trial with four groups, parallel group, triple blind

Settings and conduct

This study is performed in the medical ward of Imam Khomeini Hospital in Eesfarayen. The study population are patients referred to this wards for hospitalization. After pilot sampling, samples were randomly divided into 4 groups by using Permuted block randomization. Samples, evaluators and statistics specialists are blind to the type of protocol performed.

Participants/Inclusion and exclusion criteria

1- patients admitted to the medical and surgical department of imam khomeini Hospital, Eesfarayen 2- receiving of injection drug

Intervention groups

In the "pulsatile flushing" group prior the first drug is injected into the catheter, 1 m.l Normal saline (NS) 0.9% will be injected within 1 second (sec), then 1sec will be paused, and again 1m.l is injected within 1sec. this protocol will be repeated until 3 m.l became finish. flushing protocol will be repeated before and after drug injection. In the "continuous flushing" group prior the first drug is injected into the catheter, 3 m.l NS 0.9% will be injected within 3 sec. then, the patient drug will be injected into catheter. flushing protocol will be repeated before and after drug injection. In the saline lock group, firstly the patient's drug is injected into the catheter, then "Heparin Lock" will be attach end of the catheter and 3 ml of N.S will be injected into the catheter. In the control group, the catheter is inserted into the forearm and fixed

with glue, and drug will be injected based on medical order.

Main outcome variables

The main outcome variables including: phlebitis and catheter patency time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045773N2**

Registration date: **2020-01-31, 1398/11/11**

Registration timing: **prospective**

Last update: **2020-01-31, 1398/11/11**

Update count: **0**

Registration date

2020-01-31, 1398/11/11

Registrant information

Name

seyed javad hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3723 2650

Email address

s.j.hoseini2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Flushing and Saline Lock on phlebitis and patency time of peripheral intravenous catheters in patients admitted to the medical department

Public title

Comparing Flushing with Saline Lock on phlebitis and catheter patency

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

prescribing of ceftriaxon as a antibiotic prescribing at least two and up to three types of injection drugs within 24 hours A catheter N. 20 is inserted into the forearm Ages between 18-65 years old

Exclusion criteria:**Age**

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, patients will be selected in available and then using Permuted block randomization (four blocks) were divided into four groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Initially, the general study protocol for patients will be explained and they will be divided into one of four intervention or control groups. The study protocol is performed by a Bachelor of Science in Nursing (BSN). The catheter checking for the outcome of the study are also performed by a researcher who is not aware from type of intervention performed on the patient. The analysis is based on codes that the statistics expert does not know.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfarayen faculty of Medical Sciences

Street address

Faculty of Medical Sciences, Imam Reza St, Esfarayen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

۷۶۹۸۱-۹۶۶۱۸

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.ESFARAYENUMS.REC.1398.007

Health conditions studied**1****Description of health condition studied**

chronic obstructive pulmonary disease

ICD-10 code

J44.0

ICD-10 code description

Chronic obstructive pulmonary disease with acute lower respiratory infection

2**Description of health condition studied**

chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

3**Description of health condition studied**

pneumonia

ICD-10 code

A37.91

ICD-10 code description

Whooping cough, unspecified species with pneumonia

4**Description of health condition studied**

urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Phlebitis

Timepoint

Every 12 h for 96 h since catheter is inserted

Method of measurement

Visual Phlebitis scale

2

Description

Catheter patency

Timepoint

Every 12 h for 4 day

Method of measurement

Catheter patency checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the "pulsatile flushing" group prior the first drug is injected into the catheter, 1 m.l Normal saline (NS) 0.9% will be injected within 1 second (sec), then 1sec will be paused, and again 1m.l is injected within 1sec. this protocol will be repeated until 3 m.l became finish. flushing protocol will be repeated before and after drug injection.

Category

Prevention

2

Description

Intervention group: In the "continuous flushing" group prior the first drug is injected into the catheter, 3 m.l NS 0.9% will be injected within 3 sec. then, the patient drug will be injected into catheter. flushing protocol will be repeated before and after drug injection.

Category

Prevention

3

Description

Intervention group: In the saline lock group, firstly the patient's drugs is injected into the catheter, then "Heparin Lock" will be attach end of the catheter. 3 ml of N.S will be injected into the catheter from end of "heparin lock".

Category

Prevention

4

Description

Control group: In the control group, the catheter is inserted into the forearm and fixed with glues, and will be given caring education such as: don't soak the catheter glues and don't activity the hand that catheter is attached. drugs will be injected based on medical order.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Esfarāyen

Full name of responsible person

Eshagh Ildarabadi

Street address

Esfarayen Faculty of medical science, Imam Reza S.t, Esfarāyen Town, North khorasan, IRAN

City

Esfarayen

Province

North Khorasan

Postal code

96618-76981

Phone

+98 58 3722 6005

Email

Info@esfrums.ac.i

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfarayen University of Medical Sciences

Full name of responsible person

Eshagh Ildarabadi

Street address

Esfarayen Faculty of medical science, Imam Reza Street, Esfarāyen Town, North khorasan, IRAN

City

Esfarayen

Province

North Khorasan

Postal code

96618-76981

Phone

+98 58 3722 6005

Email

Info@esfrums.ac.i

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**

Esfarayen University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Member of esfarayen faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Esfarāyen Faculty of Medical Sciences , Imama Reza
S.t, Esfarāyen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

9661777944

Phone

0098 5831550000- 602

Email

s.j.hoseini2016@gmail.com

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

Esfarayen University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Member of Esfarayen faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Esfarāyen Faculty of Medical Sciences , Imam Reza
S.t, Esfarāyen, North Khorasan

City

Esfarayen

Province

North Khorasan

Postal code

96617-77944

Phone

+98 58 3155 0000-602

Email

s.j.hoseini2016@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfarayen University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Member of faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Esfarāyen Faculty of Medical Sciences , Imam Reza
S.t, Esfarāyen, North Khorasan, IRAN

City

Esfarayen

Province

North Khorasan

Postal code

96617-77944

Phone

+98 58 3155 0000-602

Email

s.j.hoseini2016@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Title and more details about the data/document

Document will be registered "Pajouhan" system after completion of the study . Also, participants general information and the effectiveness of interventions will be recorded in the article.

When the data will become available and for how long

Accessibility after publish of article

To whom data/document is available

People interested in nursing scope

Under which criteria data/document could be used

People looking for ways to facilitate catheter insertion in

pediatric who can access the data

From where data/document is obtainable

The information will be published as an article. Also, researchers can send an email for more information to the following Email address: s.j.hoseini2016@gmail.com

What processes are involved for a request to access

data/document

Researchers can send an email to the corresponding author and submit their request. The researcher gives his answer within 24 hours.

Comments