Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Esfarayen. 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 faculity 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