

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparing of local warming and intravenous assistive device (vein viewer) on duration and first attempt success rate for inserting of peripheral venous catheter in 1- 36 months pediatrics referred to pediatric ward of imam Khomeini hospital in esfarayen, iran

Protocol summary

Study aim

Determine effects of comparing of local warming and intravenous assistive device (vein viewer) on duration and first attempt success rate for inserting of peripheral venous catheter in 1- 36 months pediatrics referred to pediatric ward

Design

A randomized controlled clinical trial study with four groups(three intervention and one control group), parallel and randomized groups

Settings and conduct

This study is performed in pediatric ward of Imam Khomeini Hospital in Esfarayen. The study population is children (1- 36 months) referred to the pediatric ward for hospitalization. After obtaining the consent of the child's parents, they assigned in one of the four groups (local warming, vein viewer device, local heat and vein viewer device, and control group) based on a random number table.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patient should be difficult for peripheral catheter insertion (DIVA score greater than 3) 2- Age less than 36 months and more than one month. 3 - Catheter insertion is done on upper limb. Exclusion Criteria: 1- Parental unwillingness to cooperate 2- Catheter insertion Failure for first attempt 3- Patient has a emergency condition

Intervention groups

In the vein viewer device group, infra red waves illuminate 90 degrees at determined site by nurse and catheter will insert. In the local warming group, the "hot-water bottle" (40 c) will has put on for 2 minutes in site of catheterization. In the third group (local warming plus vein viewer) the "hot-water bottle" will has put on for 2 minutes then infra red waves of vein viewer device illuminated 90 degrees at determined site. In the fourth

group, nurse fasten tourniquet and based on their previous experience insert the catheter after disinfection site with Alcohol 70%.

Main outcome variables

Duration and first attempt success rate for inserting of catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045773N1**

Registration date: **2020-01-22, 1398/11/02**

Registration timing: **prospective**

Last update: **2020-01-22, 1398/11/02**

Update count: **0**

Registration date

2020-01-22, 1398/11/02

Registrant information

Name

seyed javad hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3723 2650

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15
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 of local warming and intravenous assistive device (vein viewer) on duration and first attempt success rate for inserting of peripheral venous catheter in 1- 36 months pediatrics referred to pediatric ward of imam Khomeini hospital in esfarayen, iran

Public title
Effect of local warming and vein viewer on success rate for inserting of peripheral venous catheter in pediatrics

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Age less than 36 months and more than one month.
Patients require to the insert of catheter

Exclusion criteria:
Parental unwillingness to cooperate Patient has a emergency condition.

Age
From **1 month** old to **36 months** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are randomly assigned to four groups using a random number table. Numbers 00-24 for local warming intervention, 25-49 numbers for vein viewer intervention, 50-74 numbers for local warming with vein viewer group device and numbers 75-99 are considered for the control group. The researchers then put on one of the numbers on the table of random numbers and move to the right and down of the table. We record the numbers and assign them to different groups.

Blinding (investigator's opinion)
Not blinded

Blinding description
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 S.t, Esfarayen, North Khorasan

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Esfarayen

Province

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Postal code

96618-76981

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.ESFARAYENUMS.REC.1398.008

Health conditions studied

1

Description of health condition studied

Diarrhea

ICD-10 code

R19.7

ICD-10 code description

Diarrhea, unspecified

2

Description of health condition studied

Pneumonia

ICD-10 code

A37.91

ICD-10 code description

Whooping cough, unspecified species with pneumonia

3

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

First attempt success rate for inserting of peripheral venous catheter

Timepoint

Immediately after fixation of catheter on the skin

Method of measurement

Possible to injection of "water for injection" from the Y-shaped part of the "Micro Drop Infusion Set" without causing swelling at the top of catheter insertion

2

Description

Inserting of peripheral venous catheter duration

Timepoint

Since initiation catheter insertion until it is fixed in place

Method of measurement

Using the Stopwatch

3

Description

The time spent to find a peripheral venous

Timepoint

Since the fasten of tourniquet to start inserting of peripheral venous catheter

Method of measurement

Using the Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Vein viewer device group: After fasten the tourniquet on the upper limbs (hands), nurse turn on vein viewer device (Vein light LED plus) and illuminate at 90 degrees in skin. After observing the vein, 70% alcohol is rubbed site, then the peripheral catheter N.24 will be inserted.

Category

Other

2

Description

In the intervention local warming group , Nurse fasten the tourniquet and determine a suitable vein. then, she open tourniquet and put on "hot-water bottle" (40 ° C) that wrapped in a texture(temperature will be confirmed by laser thermometer) in site of catheter insertion. it remain on the skin for 2 min. skin temperature is checked every 30 seconds. Again, the tourniquet is fastened in the upper limb and peripheral catheter will be inserted at a predetermined site.

Category

Other

3

Description

Combination Intervention group (local warming plus vein viewer device) : Nurse fasten the tourniquet and

determine a suitable vein. Then, she open tourniquet and put on "hot-water bottle" (40 ° C) in site of catheter insertion that wrapped in a texture(temperature will be confirmed by laser thermometer). It remain on the skin for 2 min. skin temperature is checked every 30 seconds. Again, the tourniquet is fastened in the upper limb, nurse turn on vein viewer device (Vein light LED plus) and illuminate at 90 degrees on skin. After observing the vein, 70% alcohol is rubbed site, then the peripheral catheter N.24 will be inserted.

Category

Other

4

Description

In control group, nurse fasten tourniquet and based on their previous experience insert the catheter after disinfection site with Alcohol 70%.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfarāyen Imam Khomeini Hospital

Full name of responsible person

Seyed Javad Hosseini

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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

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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

Master of Nursing , Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

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Latest degree

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Documentation is 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 pediatric 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

Faculty of Medical Sciences Esfarāyen, imama reza
s.tEsfarāyen, North Khorasan

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

They can access to data through below email as soon as possible s.j.hoseini2016@gmail.com

Comments