

# 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)

##### Phone

+98 58 3723 2650

##### Email address

s.j.hoseini2016@gmail.com

##### 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

##### City

Esfarayen

##### Province

North Khorasan

##### 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

#### **Street address**

Imam Reza S.t, Esfarāyen Town

#### **City**

Esfarayen

#### **Province**

North Khorasan

#### **Postal code**

96618-76981

#### **Phone**

+98 58 3722 6005

#### **Email**

s.j.hoseini2016@gmail.com

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Esfarayen University of Medical Sciences

#### **Full name of responsible person**

Eshagh Ildarabadi

#### **Street address**

Imam Reza S.t, Esfarāyen Faculty of Medical Sciences

#### **City**

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#### **Postal code**

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#### **Phone**

+98 58 3724 1604

**Email**

ldarabadi@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**

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

**Street address**

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S.t, Esfarāyen, North Khorasan

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Seyed Javad Hosseini

**Position**

Master of science- Member of faculty

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfarayen University of Medical Sciences

**Full name of responsible person**

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**Position**

Master of science- member of faculty

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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**