

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### A comparison of open vs ultrasound-guided percutaneous insertion of central venous catheter in children weighting five kilograms or less.

#### Protocol summary

##### Study aim

A comparison of open vs ultrasound-guided percutaneous insertion of central venous catheter in children weighting five kilograms or less.

##### Design

This study is a randomized clinical trial (balanced (permuted) block randomization) with the participation of 100 patients, in parallel groups with phase 2 and without blinding.

##### Settings and conduct

100 patients will be randomly divided (balanced (permuted) block randomization) into two groups (50 people in each group). Patients will go to the operating room of the Children's Hospital (Tabriz-Iran) and a central vein catheter will be inserted for them by a pediatric surgeon. The first group will receive an open catheter and the second group will receive a catheter under an ultrasound guide. No blinding will be performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included (1) weight less than 5 kg (2) required central venous catheter implantation (3) central venous catheter implantation for the first time, and (4) consent to participate in the research project and exclusion criteria also included (1) Patients with hemophilia (2) had an INR greater than 1.5 (3) platelet counts less than 100,000 (4) a history of CPR and (5) a history of coagulation disorders.

##### Intervention groups

Patients will be randomly divided (balanced (permuted) block randomization) into two groups. The first group (50 people) will receive a central venous catheter open and the second group (50 people) will receive a central venous catheter under ultrasound guidance.

##### Main outcome variables

Success rate in central venous catheter implantation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N19**

Registration date: **2020-11-06, 1399/08/16**

Registration timing: **prospective**

Last update: **2020-11-06, 1399/08/16**

Update count: **0**

##### Registration date

2020-11-06, 1399/08/16

##### Registrant information

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-30, 1399/09/10

##### Expected recruitment end date

2022-03-01, 1400/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparison of open vs ultrasound-guided percutaneous insertion of central venous catheter in children weighting five kilograms or less.

**Public title**

Central vein catheter implantation in children

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Weight less than 5 kg Requires central venous catheter placement First insertion of a central venous catheter Consent to participate in the research project

**Exclusion criteria:**

Patients with hemophilia INR rate greater than 1/5 Platelet count less than 100,000 CPR history History of coagulation disorders

**Age**

From **1 year** old to **3 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups by random allocation method. The balanced (permuted) block randomization will be used for random allocation and patients will be divided into two groups of intervention and placebo; Thus, first 6 possible modes of blocks (BAAB, ABBA, BABA, AABB, ABAB, BBAA) were listed and each block was assigned a number from 1 to 0. Then, a number between 1 and 0 was randomly selected and the subjects were assigned to the experimental group (A) and placebo (B) based on the relevant block and the selected number.

**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 Tabriz University of Medical Sciences

**Street address**

Children Hospital, Azadi Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665631

**Approval date**

2019-12-23, 1398/10/02

**Ethics committee reference number**

IR.TBZMED.REC.1398.1015

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

The rate of infection in pediatric central venous catheter implantation

**ICD-10 code**

T80.21

**ICD-10 code description**

Infection due to central venous catheter

**Primary outcomes****1****Description**

The rate of infection in pediatric central venous catheter implantation

**Timepoint**

Once daily for up to three days after catheter placement

**Method of measurement**

Clinical examinations

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients will go to the operating room. Using a linear probe , the internal jugular vein is found and then the needle is inserted into the vein. After making sure that the needle is inside the vein and reads it, the guide wire enters the lumen of the left internal jugular vein through the needle. In this case, the presence of a guide wire in the internal jugular vein can also be confirmed by ultrasound. The needle is then removed but the guide wire remains inside the vein. Using a dilator, the path is cannulated through the guide wire. After this step, the dilator is removed and the central vein catheter is inserted into the internal jugular vein through the guide wire. After making sure that the catheter is inside the vein, the guide wire is removed and the catheter will be fixed on the skin using sutures.

**Category**

Treatment - Surgery

## 2

### Description

Control group: Patients will enter the operating room. A small incision is made in the neck and the internal jugular vein is dissected and controlled, and a separate 5 mm long incision is made in the vein through which the central vein catheter is inserted without the use of a guidewire and under direct view through A venotomy is inserted, then repaired and fixed with an absorbable suture, and then the vein is repaired.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Childrens Hospital

##### Full name of responsible person

Saed Aslanabadi

##### Street address

Azadi Ave, Childrens Hospital

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5981764863

##### Phone

+98 41 3535 3696

##### Email

Salanabadi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Abolghasem Jouyban

##### Street address

Children Hospital, Azadi Ave

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##### Phone

+98 41 3335 7310

##### Email

Ajouyban@hotmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Tabriz University of Medical Sciences

### Proportion provided by this source

50

### 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Ibrahim Farhadi

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

General Surgery

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Ibrahim Farhadi

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Associate Professor

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Specialist

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Mehdi Khanbabayi Gol  
**Position**  
MSc in Nursing Education  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
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## 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 no more information

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available