

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

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

Street address

Childrens Hospital, Sheshgelan Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

Person responsible for scientific 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

Street address

Childrens Hospital, Sheshgelan Ave

City

Tabriz

Province

East Azarbaijan
Postal code
5981764863
Phone
+98 41 3334 7054
Fax
Email
Khanbabayimehdi69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863

Phone
+98 41 3334 7054
Fax
Email
Khanbabayimehdi69@gmail.com

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