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: Iran (Islamic Republic of)
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**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**
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.
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
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Sponsors / Funding sources

1

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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
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
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/ration 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