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
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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 weighing 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
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.

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

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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