Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between internal jugular central venous cannulation under ultrasound guidance and anatomical landmark method in pediatric3 months up to 6 years- randomized clinical trial

Protocol summary

Study aim

The aim of the present study was to compare the central venous cannulation of internal jugular vein using ultrasound guidance versus the anatomical landmark techniques in children aged 3 months to 6 years undergoing cardiac surgery referred to Shahid Rajaei Heart Center in Tehran.

Design

The present study is two arm, parallel, open label phase 4 randomized clinical trial that will be performed on patients undergoing cardiac surgery referred to Shahid Rajaei Heart Center in Tehran. Patients are divided into two groups: central venous catheter under ultrasound guidance (A) and anatomical landmark group (B). 120 patients are enrolled in the study. Random sequences will be generated using sealed envelope software.

Settings and conduct

In the anatomical Landmark method by the Seldinger method from the vertex of the triangle formed by the two ends of the sternocleidomastoid muscle and the clavicle bone using a 2 cc syringe (finder) with aspiration in the direction of the nipple on the same side and find the internal jugular vein and then We enter the same place and path with the main syringe and catheter. In the ultrasound guidance method, ultrasound will be performed before cannulation.

Participants/Inclusion and exclusion criteria

Children aged 3 months to 6 years Inclusion No thrombosis, No coagulation disorder, Central venous catheters, Absence of central other vein catheter, Infection, Acute infection, vascular changes exclusion Cardiopulmonary arrest

Intervention groups

Intervention Using an ultrasound device to view the carotid artery and adjacent jugular vein and insert a central venous catheter Control Central venous catheter placement based on anatomical position

Main outcome variables

Success in the first attempt at cannulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210905052379N1**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

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Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between internal jugular central venous cannulation under ultrasound guidance and anatomical landmark method in pediatric3 months up to 6 years-randomized clinical trial

Public title

Central venous cannulation under ultrasound guidance

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

No thrombosis No coagulation disorder Central venous catheters implanted or tunneled Absence of central femoral and subclavian vein catheter Infection in the puncture site Acute infection Known anatomical and/or functional vascular changes

Exclusion criteria:

Cardiopulmonary arrest

Age

From **3 months** old to **6 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using seal enveloped software. The list of blocks will be written and numbers will be assigned to them (AABB (1) - ABAB (2) -ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)), then random numbers between one and six (For example, 1 4 5, etc.) will be select and finally the treatment allocation list based on previous random numbers (AABB, BBAA, BABA, etc.) will be specified.

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

research ethics committee of Rajaie cardiovascular and medical and research center

Street address

Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection

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Tehran

Province

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Postal code

1995614331

Approval date

2021-07-31, 1400/05/09

Ethics committee reference number

IR.RHC.REC.1400.037

Health conditions studied

1

Description of health condition studied

cardiac disease

ICD-10 code

I51.9

ICD-10 code description

Heart disease, unspecified

Primary outcomes

1

Description

Success in the first attempt at cannulation

Timepoint

Immediately after catheter placement

Method of measurement

Fill out the questionnaire

Secondary outcomes

1

Description

Cannulation time

Timepoint

After catheter placement

Method of measurement

Fill out the questionnaire

2

Description

Additional venous site puncture

Timepoint

Not applicable

Method of measurement

Fill out the questionnaire

3

Description
Incidence of mechanical complications
Timepoint
After cannulation
Method of measurement
Fill out the questionnaire

Intervention groups

1

Description
After induction of anesthesia and sterilization, and by using an ultrasound device and movement of the probe over the carotid artery and the adjacent jugular vein, the location of the vein is confirmed. The catheter is then inserted.
Category
Diagnosis

2

Description
In the anatomical landmark control group, after induction of anesthesia, a catheter is placed at the apex of the triangle, which consists of two parts of the sternocleidomastoid muscle and the right clavicle, according to the anatomical position of the central vein.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research-MC@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Roxana Rastravan
Position
Anesthesiology Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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