

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison between internal jugular central venous cannulation under ultrasound guidance and anatomical landmark method in pediatric 3 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

Name

Ali Sadeghi

Name of organization / entity

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

Country

Iran (Islamic Republic of)

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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 pediatric 3 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
City
Tehran
Province
Tehran
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

Ali sadeghi

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Shaheed Rajaie Cardiovascular Medical and Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Samideh Khoei

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Sadeghi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Full name of responsible person

Roxana Rastravan

Position

Anesthesiology Fellowship

Latest degree

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Other areas of specialty/work

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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