

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the two different methods of the internal jugular central venous catheter in infants under one-month-old

Protocol summary

Study aim

Comparing the two different methods of the internal jugular central venous catheter in infants under one-month-old

Design

A parallel-group, double-blind, simple randomized, N/A phase clinical trial on 64 patients

Settings and conduct

Patients hospitalized in Mofid Hospital were randomly assigned to needle (22 G) or angiocath (22 G) catheterizations. After general anesthesia, patients are placed in the Trendelenburg 30 position and after sterilizing the skin, catheterization is performed by a pediatric anesthetist or fellowship under ultrasound guidance. The primary site of choice for catheterization is the right internal jugular vein. In case of unsuccessful catheterization, it will be done in the left internal jugular vein. Patients and their families were blinded to group allocation. Also, the data analyzer was blinded to the assigned group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infants under one month old who are candidates for central venous catheterization. The lack of access to a suitable peripheral vein in critically ill babies who are hospitalized for a long time or need TPN (total parenteral nutrition). Exclusion criteria: Central vein anomalies, catheter site thrombosis, catheter site infection.

Intervention groups

The group of internal jugular central vein catheterization with needle and angiocath in babies under one month.

Main outcome variables

The number of attempts for successful venipuncture. The time required for successful venipuncture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051197N2**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **prospective**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

Registrant information

Name

Malek Moien Ansar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0884

Email address

ansarmoiens@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the two different methods of the internal jugular central venous catheter in infants under one-month-old

Public title

Comparing the two different methods of the internal jugular central venous catheter in infants under one-month-old

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

infants under one month old who are candidates for central venous catheterization The lack of access to a suitable peripheral vein in critically ill babies who are hospitalized for a long time or need TPN (total parenteral nutrition)

Exclusion criteria:

Central vein anomalies catheter site thrombosis catheter site infection

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and their families were blinded to group allocation. Also, the data analyzer was blinded to the assigned group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

4167811969

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.191

Health conditions studied**1****Description of health condition studied**

During aspiration, puncture and other catheterization

ICD-10 code

Y60.6

ICD-10 code description

During aspiration, puncture and other catheterization

Primary outcomes**1****Description**

The number of attempts for successful venipuncture

Timepoint

During the procedure

Method of measurement

Number

2**Description**

The time required for successful venipuncture

Timepoint

During the procedure

Method of measurement

minute

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Needle (22 G) catheterizations. After general anesthesia, patients are placed in the Trendelenburg 30 position and after sterilizing the skin, catheterization is performed by a pediatric anesthetist or fellowship under ultrasound guidance. The primary site of choice for catheterization is the right internal jugular vein. In case of unsuccessful catheterization, it will be done in the left internal jugular vein.

Category

Treatment - Surgery

2**Description**

Intervention group: Angiocath (22 G) catheterization. After general anesthesia, patients are placed in the Trendelenburg 30 position and after sterilizing the skin, catheterization is performed by a pediatric anesthetist or fellowship under ultrasound guidance. The primary site of choice for catheterization is the right internal jugular vein. In case of unsuccessful catheterization, it will be done in the left internal jugular vein.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Hospital

Full name of responsible person

Dr. Seyyed Alireza Mahdavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Mahdavi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

Regarding the ethical issues

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available