

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of the complications of inter and post operation of central vein catheterization (CVC) of internal jugular vein in repaired and cut down method in neonates

Protocol summary

Summary

Goal: to compare the complications of inter and post operation of central vein catheterization (CVC) of internal jugular vein in repaired and cut down methods in 71 Neonates under 30 days. In repair method cases were positioned in trendelenburg (30 degree) position. After fixing the head in a hyper extended position, it was turned to the left. Catheterization was done using a luminal broviac catheter (14-16 G) under anesthetic monitoring. After the local anesthesia (Lidocaine 1%) on Sternocleidomastoid (SCM) an incision (2 Cm) was made. Following the dissection of subcutaneous tissue and platysma muscle, the SCM was exposed. On the anterior Portion a space was made and internal Jugular vein below the muscle was identified. Using a silk Suture (3-0) both ends of vein was elevated. Then in the lateral Portion of the nipple (6-8 Cm from the incision) under the influence of local anesthesia a small incision was made and through a subcutaneous canal central venous canal (CVC) was moved to the neck region. Cutting on the vein, lateral side of the vein wall was opened to let the Catheter to move inside. Making an aspiration with a syringe provided the efficacy of the Catheter. The site of catheter cut was narrowed using a prolis suture (6-0) to prevent the bleeding. On termination, the Catheter was fixed on the skin and the site of catheterization was verified using a chest graphy. In cutdown method the procedure was the same with the exception that after the exposure of internal Jugular vein, at first the proximal side of the vein was ligated using a silk suture (3-0) and the Catheter was guided towards the distal lumen of internal Jugular vein and fixed on the skin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010241106N3**

Registration date: **2010-12-09, 1389/09/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-09, 1389/09/18

Registrant information

Name

Zohreh Azarbad

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kashan University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the complications of inter and post operation of central vein catheterization (CVC) of internal jugular vein in repaired and cut down method in neonates	
Public title	Comparison of the complications of inter and post operation of central vein catheterization (CVC) of internal jugular vein in repaired and cut down method in neonates.
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Neonates under 30 days with an indication of CVC. Exclusion criteria: Neonates with severe coagulatory disorders; Contraindicated for CVC; non-reluctant to follow-up and Doppler Sonography; failure and inability in catheterization.
Age	From 1 year old to 30 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 71
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Deputy of Research, Kashan University of Medical Sciences
Street address	5th kilometer of Ravand Road
City	Kashan
Postal code	8715988141
Approval date	2010-09-28, 1389/07/06
Ethics committee reference number	1919/1/5/29پ

Health conditions studied	
<u>1</u>	
Description of health condition studied	Lack of peripheral venous access
ICD-10 code	Y65
ICD-10 code description	Other misadventures during surgical and medical care
Primary outcomes	
<u>1</u>	
Description	success of central vein catheterization of internal jugular vein in cut down method
Timepoint	preioperation until end of admission
Method of measurement	Examination and Chest x-ray
Secondary outcomes	
<u>1</u>	
Description	bleeding
Timepoint	preioperation
Method of measurement	observation
<u>2</u>	
Description	arterial perforation
Timepoint	preioperation
Method of measurement	observation
<u>3</u>	
Description	hematoma
Timepoint	preioperation until 1 hour later
Method of measurement	observation
<u>4</u>	
Description	obstruction in thoracic duct
Timepoint	preioperation until 72 hour later
Method of measurement	physical exam and X-ray

5

Description

emboli

Timepoint

preioperation

Method of measurement

observation

6

Description

hydrothorax

Timepoint

preioperation until 72 hour later

Method of measurement

vital sgin and chest x-ray

7

Description

Spontaneous withdrawal catheter

Timepoint

until 72 hours postoperative

Method of measurement

observation

8

Description

haemothorax

Timepoint

preioperation until 72 hour later

Method of measurement

vital sgin and chest x-ray

9

Description

Heart Arrhythmia

Timepoint

Intraoperative

Method of measurement

Heart monitoring

10

Description

pneumothroax

Timepoint

preioperation until 72 hour later

Method of measurement

vital sgin and chest x-ray

11

Description

Tamponade

Timepoint

preioperation until 72 hour later

Method of measurement

vital sgin and chest x-ray

12

Description

failure in catheter insertation

Timepoint

Intraoperative

Method of measurement

observation

13

Description

thrombosis

Timepoint

until 3 months postoperative

Method of measurement

Sonography Doppler

14

Description

Surgical site infections

Timepoint

until 72 hours postoperative

Method of measurement

Examination and culture samples

Intervention groups

1

Description

central vein catheterization of internal jugular vein in cut down method

Category

Treatment - Surgery

2

Description

central vein catheterization of internal jugular vein in repaired method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Dr. Mehrdad. Hosseinpoor

Street address

5th kilometer of Ravand Road

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

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5th kilometer of Ravand Road

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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

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty