

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Optimal dose of heparin for patency of peripherally inserted central catheter

Protocol summary

Summary

This randomized clinical trial was conducted on 89 very low birth weight neonates. The infants were randomly allocated to either the low dose or high dose group by a simple randomization method using a table of random numbers. The low dose group was administered with 1.5 unit of heparin in each hour for one another of kilogram of body weight. high dose group received 0.5 unit of heparin for one another of milliliter of serum. blindness was done for information assessment committee. The external part of catheter was covered with sterile transparent cover. The primary outcome was the duration of time that catheter was open and not experienced occlusion. Catheter occlusion was defined as inability to push 1 cc of normal saline 0.9% with 5 milliliter syringe. The secondary outcomes were incidence of sepsis, catheter related sepsis, phlebitis, heparin induced thrombocytopenia, skin reaction, IVH and grade of IVH, blood pressure fluctuation, death rate and other cause of catheter removal (such as termination of therapy, leakage and rupture of catheter, sudden exit of catheter)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060621910N3**

Registration date: **2017-06-16, 1396/03/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-16, 1396/03/26

Registrant information

Name

Behzad Barekatin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6670

Email address

b_barekatin@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Optimal dose of heparin for patency of peripherally inserted central catheter

Public title

Evaluating the effect of high dose versus low dose of heparin in patency of peripherally inserted central catheter in very low birth weight infants in alzahra and shahid beheshti hospitals in Isfahan at 1395-1396

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: preterm infants with birth weight less than 1500 gram; An informed consent obtained from patients parents; infant needs total parenteral nutrition;

long-term IV medication administration; administration of hyperosmolar IV fluids. Exclusion criteria: Skin infection at insertion site; uncorrected bleeding diathesis; ongoing bacteremia or fungal infection; follow up impossibility during study.

Age

To **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The infants were randomly allocated to either the low dose or high dose group by a simple randomization method using a table of random numbers

Secondary Ids

empty

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

Ethics committee of Isfahan University of Medical Science

Street address

Hezarjerib boulevard, Isfahan University of Medical Science

City

Isfahan

Postal code**Approval date**

2015-11-02, 1394/08/11

Ethics committee reference number

IR.MUI.REC.1394.1.142

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

Neonatal Sepsis

ICD-10 code

P36.9

ICD-10 code description

Bacterial sepsis of newborn, unspecified

2**Description of health condition studied**

Intra Ventricular Hemorrhage

ICD-10 code

P52.9

ICD-10 code description

Intracranial (nontraumatic) haemorrhage of fetus and newborn, unspecified

3**Description of health condition studied**

Catheter Related Sepsis

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

4**Description of health condition studied**

Phlebitis

ICD-10 code

T82.8

ICD-10 code description

Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

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

Duration of Catheter Patency

Timepoint

Daily

Method of measurement

With Normal Saline and 5 cc Syringe

Secondary outcomes**1****Description**

Catheter Related Sepsis

Timepoint

during Study

Method of measurement

Culture of Catheter Tip

2**Description**

Intra Ventricular Hemorrhage

Timepoint

3th and 14th and 21th days

Method of measurement

3**Description**

Phlebitis

Timepoint

During Study

Method of measurement

Observation and Physical Examination

4**Description**

Sepsis

Timepoint

During Study

Method of measurement

Clinical Sign and Blood Culture

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

In Intervention Group we prescribed 1/5 u/kg/h of Heparin Via PICC

Category

Prevention

2**Description**

In Control Group we prescribed ./5 u Heparin/1 cc of Serum Via PICC

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Behzad Barekatin

Street address

Isfahan, Sofeh street

City

Isfahan

2**Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Behzad Barekatin

Street address

Isfahan, Metal Bridge

City**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Isfahan University of Medical Science

Full name of responsible person

Mehdi Nematbakhsh

Street address

Hezarjerib boulevard, Isfahan University of Medical Science

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Isfahan University of Medical Science

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**

Isfahan University of Medical Sciences

Full name of responsible person

Ladan Salamaty

Position

Fellowship of Neonatology

Other areas of specialty/work**Street address**

Pediatric office, Imam hosein hospital, Imam khomeini street,

City

Isfahan

Postal code**Phone**

00

Fax**Email**

ladan_salamaty@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Behzad Barekatin

Position

Academic member of Isfahan University of Medical Sciences, Neonatologist

Other areas of specialty/work**Street address**

Nom 302, Arian apartment building, Mehran ave, Moshtagh st, Isfahan

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Person responsible for updating data

Contact

Name of organization / entity**Full name of responsible person****Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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Web page address

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