

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of continuous heparin infusion on the duration of open peripheral central venous catheter (PICC) patency in preterm neonates

Protocol summary

Study aim

The effect of continuous heparin infusion on the duration of peripheral central venous catheter (PICC) patency in preterm neonates

Design

This clinical trial has a control group, with a case group (administration of 0.5 U / ml / hr intravenous fluids), randomized, double blind. The sample size will be 100 in each group.

Settings and conduct

All preterm infants (gestational age less than 34 weeks) admitted to the NICU ward of Alzahra Hospital in Tabriz, who according to the neonatal specialist, require a PICC catheter. Then premature infants with a properly implanted catheter will be randomly divided into two groups of heparin and normal saline recipients, who will not be responsible for dividing the randomes in the follow-up study. In this study, physicians, nurses, and researchers will be blind to the study groups.

Participants/Inclusion and exclusion criteria

All preterm infants (gestational age less than 34 weeks) admitted to the NICU ward of Alzahra Hospital in Tabriz, who according to the neonatal specialist, require a PICC catheter. All preterm infants (less than 34 weeks gestational age) admitted to the NICU ward of Alzahra Hospital in Tabriz will be included in the study, according to the neonatal specialist, who require a PICC catheter. Neonates with bleeding potential, grade 3 and 4 intravascular hemorrhage, newly diagnosed sepsis, thrombocytopenia, DIC, arrhythmia, and congenital malformations will be excluded. Also increased PTT (more than 71 seconds) and neonates needing to receive heparin will be excluded.

Intervention groups

Two groups of heparin and normal saline

Main outcome variables

The primary outcome is the duration of catheter use, ie the time between insertion and exit of the catheter due to obstruction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140921019250N2**

Registration date: **2020-02-20, 1398/12/01**

Registration timing: **retrospective**

Last update: **2020-02-20, 1398/12/01**

Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Majid Mahallei

Name of organization / entity

Department of Pediatrics, Tabriz University of Medical Sciences.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2019-08-23, 1398/06/01

Scientific title

The effect of continuous heparin infusion on the duration of open peripheral central venous catheter (PICC) patency in preterm neonates

Public title

The effect of continuous heparin infusion on the duration of central venous catheter patency in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All premature infants (gestational age less than 34 weeks) admitted to NICU ward of Alzahra hospital in Tabriz who require PICC catheter insertion

Exclusion criteria:

Infants with a bleeding tendency Grade 3 and 4 intravascular hemorrhage Newly diagnosed sepsis Thrombocytopenia DIC arrhythmia Congenital malformations Increased PTT (more than 71 seconds) Babies in need of heparin Babies in need of heparin

Age

To **9 months** old

Gender

Both

Phase

4

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **126**

Actual sample size reached: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, all patients will be given a code and all codes will be randomly divided into two groups using randomization software. Only the person responsible for collecting the patient information and results were aware of this coding.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient information will be provided by the treating physician as well as the type of treatment and the type of each patient's coding, and only one person who is responsible for collecting study results and data and has no role in the treatment will know the coding. Treatment will also be provided to each individual in similar containers by a person responsible for collecting study results and data that does not play a role in the treatment coded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences.

Street address

Daneshgah Street

City

Tabriz

Province

North Khorasan

Postal code

0

Approval date

2019-09-27, 1398/07/05

Ethics committee reference number

IR.TBZMED.REC.1398.573

Health conditions studied

1

Description of health condition studied

Premature babies

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

Duration of catheter use is the time between insertion and exit of the catheter due to obstruction

Timepoint

On the first and seventh day, and immediately after the catheter was removed

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study group (administration of intravenous fluids containing 0.5 U / ml / hr) will receive two dextrose-based injections containing amino acid and lipid. Unbroken heparin will also be used.

Category

Treatment - Drugs

2

Description

Control group: The study group (administration of intravenous fluids containing dextrose serum at a dose of 0.5 U / ml / hr) will receive two dextrose-based injections containing amino acid and lipid.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Dr Majid Mahallei

Street address

Alzahra Hospital of Tabriz University of Medical Sciences, Artesh Street, Tabriz, Eastern Azerbaijan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hasan Soleimanpour

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Majid Mahallei

Position

Subspecialty of Neonates.

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

Not applicable

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