

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Early Outcome of peripheraly inserted central catheter(PICC)versus peripheraly conulation(PC) in very low birth weight (VLBW)infants. infants

Protocol summary

Summary

We conducted this randomized clinical trials for studding Early Outcome of Peripherally Inserted Central Catheter (PICC) versus peripheraly Intravenous line(PIV) in Very Low Birth Weight preterm infants.In this research 114 VLBW infants who are inborn in Alzahra teaching hospital after 3-7 days of birth; randomly will divide in two groups afte robtaining consent from the parents . For the first group peripherally Intravenous line and for second group PICC catheter will be inserted. All the infants for the first 3-7 day would have umbilical vein catheter.All tubing and conections will be change every day and dressing whenever it need too.At the time of PICC orPIV extraction a culture from the tip of the Catheres will be sent for detecting of colonization.Catheter-related bloodstream infection, hospital stay, mortality rate and local complications will be compared between two groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903204113N2**
Registration date: **2012-11-28, 1391/09/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz Universisty of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Pediatric health research center of Tabriz university of Medical scineces

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early Outcome of peripheraly inserted central catheter(PICC)versus peripheraly conulation(PC) in very low birth weight (VLBW)infants. infants

Public title

Benefits and complication of peripheraly inserted central catheter (PICC) versus peripheraly Intravenous Vein lines

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Very Low Birth Weight neonates who will be born in Al-Zahra teaching hospital of Tabriz; without lethal congenital anomaly and chromosomal disorders; Absent major congenital heart disease; Absent hemorrhagic disorders; Absent generalized skin disorders

or skin infection in the site of catheter insertion; Stability of vital signs according to the opinion of Neonatologist
Exclusion criteria: All contraindications for PICC insertion (coagulopathy; venous thrombosis; generalized skin disorders or skin infection in the site of catheter insertion; Transport the neonate to another medical centres.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz Golgasht street. Medical University

City

Tabriz

Postal code

51666_14766

Approval date

2012-07-02, 1391/04/12

Ethics committee reference number

9184

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

Very low Birth Weight Infants

ICD-10 code

p07.1

ICD-10 code description

Birth weight between 1000-2499 grams

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

Catheter-related bloodstream infection

Timepoint

From cathrter insertion time to discharge from hospital

Method of measurement

With clinical symptom and paraclinical evidences specially blood culture

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

Mortality rate

Timepoint

From the admission until death time

Method of measurement

according to patient dossier

2**Description**

hospital stay duration

Timepoint

Hospitalization days from admission until discharge or death

Method of measurement

according to dossier data

3**Description**

local complication such as skin infection

Timepoint

From insertion until remove of catheter

Method of measurement

Observation by nursing staff

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

After randomization in two parallel groups, UVC will remove and a PICC will place at 3-7 days after birth in one group of the study. Using sterile technique, one specially trained neonatal nurse with cooperation of Neonatology fellowship will place the PICCs. Catheters made by Vygon company with 2 French caliber with breakable introducer needles will use. Three betadine swabs, with at least 1 min drying time for each, will be use when placing the PICCs. All PICCs will place in the upper limbs; placement of these lines will confirm at T4 to T6 level by radiograph. Trained nurses are responsible for changing the PICC dressings. The PICCs will monitor daily to ensure that the PICC dressing is occlusive. when

necessary, the dressing will change.

Category

Other

2

Description

In the other group after removing UVC with a clean technique, place the peripheral IV lines.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital of Tabriz

Full name of responsible person

Dr, Mohanad Bagher Hossaini

Street address

Alzahra Teaching Hospital, Artesh Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pediatric health research center of Tabriz university of medical sciences

Full name of responsible person

Dr. Mohammad Barzegar

Street address

Pediatric Hospital , Sheshgelan Street

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pediatric health research center of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ahmmad Safary

Position

Assistant of Neonatology

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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