

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1553 9161

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hossainm@tbzmed.ac.ir

##### 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 peripherally inserted central catheter (PICC) versus peripherally 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 removal 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 be placed 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 be used. Three betadine swabs, with at least 1 min drying time for each, will be used when placing the PICCs. All PICCs will be placed in the upper limbs; placement of these lines will be confirmed at T4 to T6 level by radiograph. Trained nurses are responsible for changing the PICC dressings. The PICCs will be monitored 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

**City**

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

**Other areas of specialty/work**

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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*