

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of different strategies for vascular access in ELBW infants in NICU

#### Protocol summary

Registration date: **2022-12-25, 1401/10/04**  
Registration timing: **prospective**

#### Study aim

Comparison of 3 different strategies for vascular access in ELBW infants

Last update: **2022-12-25, 1401/10/04**  
Update count: **0**

#### Design

Clinical trial in three parallel groups, single blind (blinding for the data analysis team), randomized with block randomization technique, individual randomization unit and using RAS software.

#### Registration date

2022-12-25, 1401/10/04

#### Settings and conduct

Extremely low birth weight infants admitted to the neonatal intensive care unit of Mahdiyeh Hospital in Tehran will be included in the study. For the venous access of these infants, one of the three strategies mentioned above will be chosen. These babies will be followed up during hospitalization in terms of three main outcomes. Blinding will only be possible for the data analysis team.

#### Registrant information

##### Name

Elahe Rastkar Mehrabani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5506 2628

##### Email address

elaheh.rastkar86@yahoo.com

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: infants with birth weight less than 1000 grams who will be admitted in NICU; Exclusion criteria: congenital abnormalities, parents who are not consent to be in this research, insertion of UVC in delivery room in resuscitation process

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Intervention groups

A: insertion of PICC at first day of life B: insertion of UVC at first day of life . then removal of UVC at day 5 to 7 and insertion of PICC same day C: insertion of PIV at first day of life then then removal of PIV at day 5 to 7 and insertion of PICC same day

#### Expected recruitment start date

2023-01-21, 1401/11/01

#### Expected recruitment end date

2025-01-20, 1403/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Neonatal Death, Central Line Associated Blood Stream Infection, Intra ventricular Hemorrhage

#### Trial completion date

empty

#### General information

#### Scientific title

Comparison of different strategies for vascular access in ELBW infants in NICU

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220704055362N1**

#### Public title

Effect of type of vascular access in neonatal outcomes

#### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
All of neonates with birth weight less than 1000 grams who will be admitted in neonatal intensive care unit of Mahdiyeh hospital

**Exclusion criteria:**  
Congenital abnormalities Insertion of Umbilical venous catheter in delivery room in resuscitation process parents do not consent to be in this research

**Age**  
From **1 day** old to **1 day** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **183**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The classification of the samples to be assigned to the treatment groups will be done in a block random manner. The randomization unit is considered individual. RAS statistical software, block randomization tool will also be used to determine the sequence of blocks. The sealed cover letter will be used for allocation concealment. We consider the capacity of the blocks as 6 and then we write all the possible permutations for this block, which are defined as follows. (1: ABCABC) and (2: AABCC) and (3: BBCCAA) and (4: BACBAC) and (5: ACBBCA) and (6: BCACAB) and... By means of statistical software, we randomly select one of the numbers of permutations and consider the block corresponding to it. For example, if the first random selection of block 5 is selected, the first person will receive treatment A, the second person will receive treatment C, the third and fourth persons will receive treatment B, the fifth person will receive treatment C, and the sixth person will receive treatment A. To reach a sample size of 61 in each stratum, we continue this process 31 times. After selecting all the blocks, we randomly assign A, B, C to one of the treatment groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Due to the nature of the study, blinding will only be possible for the data analysis group, and this group will not know what type of intervention groups A, B, and C have received.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

##### Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419943471

#### Approval date

2022-11-13, 1401/08/22

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1401.558

## Health conditions studied

### 1

#### Description of health condition studied

Neonates with birth weight less than 1000 grams

#### ICD-10 code

P07.0

#### ICD-10 code description

Extremely low birth weight newborn

## Primary outcomes

### 1

#### Description

Central Line Associated Blood Stream Infection

#### Timepoint

Since 24 hours after insertion of central line till 48 hours after removal. In this period whenever neonate has clinical signs of infection, blood culture will be sent.

#### Method of measurement

Positive blood culture in an neonate with a central venous catheter with clinical symptoms, with no other known source of infection

## Secondary outcomes

### 1

#### Description

Inter ventricular hemorrhage

#### Timepoint

Three days after birth and then weekly for a month

#### Method of measurement

Reviewing of brain ultrasound report

## 2

### **Description**

Neonatal mortality

### **Timepoint**

From birth to 28 days old. Whenever it happens

### **Method of measurement**

Direct observation and record in the medical record file

## **Intervention groups**

### 1

#### **Description**

Intervention group: in this group Peripherally inserted Central Catheter (PICC) line will be inserted at first day of life

#### **Category**

Treatment - Devices

### 2

#### **Description**

Intervention group: In this group Umbilical Venous Catheter (UVC) will be inserted at first day of life and at day 5 to 7, UVC will be removed and Peripherally Inserted Central Catheter (PICC) will be inserted

#### **Category**

Treatment - Devices

### 3

#### **Description**

Intervention group: In this group Peripheral Inter venous (PIV) catheter will be inserted at first day of life and 5 to 7 days later PICC will be replaced

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mahdiyeh Hospital

##### **Full name of responsible person**

Ali Naseh

##### **Street address**

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1185817311

##### **Phone**

+98 21 5506 2628

##### **Fax**

+98 21 5506 2627

##### **Email**

mahdiyeh\_hospital@sbmu.ac.ir

##### **Web page address**

https://mmc.sbmu.ac.ir/

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

افشین زرقی

##### **Street address**

Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

198396-3113

##### **Phone**

+98 21 23871

##### **Email**

info@sbmu.ac.ir

##### **Web page address**

https://sbmu.ac.ir/

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Elahe Rastkar Mehrabani

##### **Position**

NICU nurse

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

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**Email**

e.rastkar@sbmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Naseh

**Position**

Assistant Professor of Neonatal-Perinatal Medicine

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elahe Rastkar Mehrabani

**Position**

NICU nurse

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**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