Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
Comparison of 3 different strategies for vascular access in ELBW infants
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.
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.
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
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
Main outcome variables
Neonatal Death, Central Line Associated Blood Stream Infection, Intra ventricular Hemorrhage

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220704055362N1**
Registration date: **2022-12-25, 1401/10/04**
Registration timing: **prospective**

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

Registrant information
Name
Elahe Rastkar Mehrabani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

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
Trial completion date
empty

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

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: AABBCC) 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
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Phone
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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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Person responsible for updating data

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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