Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of head positioning on the tissue oxygenation of brain in preterm infants

Protocol summary

Study aim
Determination of the effect of head positioning on the tissue oxygenation of brain in preterm infants.

Design
A clinical trial with a control group, crossover, single blind, Randomized by generating random numbers by SPSS software with sample size 30.

Settings and conduct
In the NICU ward of Umm al-Banin Hospital, 30 infants are treated within the first 48 hours after birth who meet the inclusion criteria. During the intervention, tissue oxygenation of the brain is recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infant age less than or equal to 32 weeks; Infant weight less than 1500 grams; Infant stable condition (non Invasive mechanical ventilation and hemodynamic status stable neonate)Have; Apgar score of first minute exceeds 5 and fifth minute greater than 7;A hemoglobin level greater than or equal to 12 g / dl. mean arterial blood pressure(MAP) were within normal range.Exclusion criteria: Congenital and chromosomal abnormalities; Intrauterine growth restriction (IUGR) ; known intracranial hemorrhage; recipient of dense red blood cell product.

Intervention groups
In the intervention group, infants are placed in supine position and every 2 hours the head is switched to one of 6 modes [1 midline head and 0° bed head .2 The head rotates 60-45 ° from the midline to the left and the bed head 0°. 3 The head rotates 60-45 ° from the midline to the right and the bed head 0°.4 midline head position with the bed head 15- 30°, 5 The head rotates 60-45 ° from the midline to the left and the bed head 15- 30°. 6 The head rotates 60-45 ° from the midline to the right and the bed head 15- 30°].During each head positioning,tissue oxygenation of brain is recorded by the NIRS device .infants under intervention are also used as their control group.To this end, the data are compared before and after their intervention.

Main outcome variables
tissue oxygenation of brain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190826044623N1**
Registration date: **2019-10-17, 1398/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-17, 1398/07/25**
Update count: **0**

Registration date
2019-10-17, 1398/07/25

Registrant information
Name
Zeinab Rabbani Mohammadie
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
2019-09-06, 1398/06/15
Expected recruitment end date
2020-03-05, 1398/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of head positioning on the tissue oxygenation of brain in preterm infants

Public title
The effect of head positioning on the tissue oxygenation of brain

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The age of the infant on a Ballard basis is less than or equal to 32 weeks at the time of study. infant weight under 1500 grams. neonate stable condition (non Invasive mechanical ventilation and hemodynamic status stable neonate)Have. Apgar score of first minute exceeds 5 and fifth minute greater than 7. A hemoglobin level greater than or equal to 12 g / dl. Mean arterial blood pressure (MAP) is within normal range.

Exclusion criteria:
The infant will have have congenital and chromosomal abnormalities. The infant have intrauterine growth restriction (IUGR) . The infant receiving the red blood cell product is dense. The infant with known intracranial hemorrhage.

Age
To **8 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
All possible sequence combinations are coded for 6 study positions in SPSS software, 720 modes. We assign a unique number to each position. In the study sample number, random numbers are generated by SPSS software. Hence the random modes of the research units are obtained.Write each of the modes in a separate card and put all the cards in a package. For each research unit, we remove and use one of the cards from the envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyst will be unaware of the intervention and control groups.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of School of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address
Unit 1, Floor 1,No. 154, Vilaye 7

City
Mashhad

Province
Razavi Khorasan

Postal code
9171618995

Approval date
2019-07-21, 1398/04/30

Ethics committee reference number
IR.MUMS.NURSE.REC.1398.040

Health conditions studied

1

Description of health condition studied
The effect of head positioning on the tissue oxygenation of brain in preterm infants

ICD-10 code
P52.3

ICD-10 code description
Unspecified intraventricular (nontraumatic) hemorrhage of newborn

Primary outcomes

1

Description
tissue oxygenation of brain

Timepoint
After every two hours of head positioning, tissue oxygenation of brain is recorded by the NIRS device.It should be noted that before the intervention, the tissue oxygenation of brain of each infant is measured and recorded within ten minutes to obtain the baseline value for each infant and compare with subsequent values.

Method of measurement
NIRS device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, infants are placed in supine position and every 2 hours the head is switched to one of 6 modes [1 midline head and 0° bed head .2 The head rotates 60-45 ° from the midline to the left and the bed head 0°. 3 The head rotates 60-45 ° from the midline to the right and the bed head 0°.4 midline head position with the bed head 15- 30°, 5 The head rotates 60-45 ° from the midline to the left and the bed head 15- 30°. 6 The head rotates 60-45 ° from the midline to the right and the bed head 15- 30°].During each head positioning, tissue oxygenation of brain is recorded by the NIRS device. The infants under intervention are also used as their control group. And according to the routine inpatient treatment center, they receive their medical care before the intervention, and brain tissue oxygenation data are collected and compared with post-intervention data.And they are also used as witnesses for this purpose.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
UmmOl-Banin Hospital

Full name of responsible person
Monir Ramezani

Street address
UmmOl-Banin Hospitalon, Corner of Ayatollah Behjat 16, Zarineh Intersection

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ramezanimn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Robab Latifnejad Rodsari

Street address
School of Nursing and Midwifery, Ibn Sina Street, Doctora crossroads, Danshgah street,

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latifnejadr@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zeinab Rabbani Mohammadie

Position
Master of student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Unit 1, Floor 1, No. 154, Villaye 7

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after unidentifiable people.

When the data will become available and for how long
The access period starts 2 months after the results are published.

To whom data/document is available
The data are made available to researchers working in academic and scientific institutions, and to those involved in the industry as well as to the Ministry.

Under which criteria data/document could be used
If positive, this study could lead to a caring approach for the premature infant within the first 72 hours after birth, which improves brain oxygenation and hemodynamics and reduces the chance of occurrence and severity of intraventricular hemorrhage in the premature infant.

From where data/document is obtainable
Zeinab Rabbani Mohammadie:rabbanimz961@mumc.ac.ir,Phone Call:00989910435332 Dr Monir Ramezani:ramezanimn@mums.ac.ir,Phone Call:00989124186326

What processes are involved for a request to access data/document
The applicant should contact through the given contact number and e-mail.

Comments