Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mother’s bosom like position on the duration of sleep in premature neonates.

Protocol summary

Study aim
Determining the duration of sleep of premature infants after feeding in the supine position in the baby's nest in the control group Determining the duration of sleep of an premature infant after feeding in the supine position similar to the mother's arms in the intervention group Comparison of sleep duration of premature infants after feeding in the control group and the intervention group

Design
Crossover

Settings and conduct
NICU, Ommol Banin hospital, Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria
Pregnancy age 31 to 34 weeks • Birth weight 1500 to 2000 kg • Feed the baby every 2 hours

Intervention groups
Assess sleep in premature newborn

Main outcome variables
situation of sleep in newborn

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140610018046N4**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **retrospective**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date
2020-09-16, 1399/06/26

Registrant information

Name
Sedighe Khanjari

Name of organization / entity
School of Nursing and Midwifery, Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8867 1613

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-04, 1399/03/15

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mother’s bosom like position on the duration of sleep in premature neonates.

Public title
Sleep in premature neonates

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnancy age 31 to 34 weeks; Birth weight 1500 to 2000 kg; Feed the baby every 2 hours; No restriction on position change; Self-breathing without the need for respiratory support; Lack of congenital disease or brain defects such as intraventricular hemorrhage; Do not use sedatives 24 hours before the study; Failure to perform painful invasive interventions such as vessel sampling or

sampling 12 hours before the start of the study; Do not use phototherapy; Failure to use tobacco by the mother or substance abuse during pregnancy; Normal blood sugar

Exclusion criteria:

Need immediate medical attention while studying Blood infection Seizures

Age

From **1 day** old to **15 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in this study was performed by continuous sampling . Eligible infants were randomly assigned to quadruple blockade in two intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

A crossover design selected to reduce the effect of interfering factors

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

14665-354

Approval date

2019-10-28, 1398/08/06

Ethics committee reference number

IR.IUMS.REC.1397.721

Health conditions studied

1

Description of health condition studied

sleep in premature neonates.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

situation of sleep in immature neonate

Timepoint

The first week

Method of measurement

Amplitude-integrated Electroencephalography

Secondary outcomes

1

Description

Mother’s bosom like position on the duration of sleep in premature neonates

Timepoint

Immediately after feeding for two hours in the supine position on the baby's nest

Method of measurement

Sleep status was evaluated by aEEG

Intervention groups

1

Description

Intervention group: After feeding and connecting the electrodes, the baby was first placed in a nest appropriate for his size in the same position as the mother's arms, and his brain tape was recorded for 2 hours using an aEEG device. To prevent the effect of the intervention in the control group, the infant was placed in the wash out stage for 2 hours, and the electrodes were reconnected to his head and placed in his nest lying on his stomach while his head was turned to one side. Similarly, his brain tape was recorded by the aEEG device within 2 hours. Due to the fact that the research environment was low traffic between 14:00 and 20:00 and the number of medical procedures and nursing care was minimal, the study was conducted during this period.

Category

N/A

2

Description

Control group:In the control group, immediately after feeding, three electrodes of the aEEG device were

attached to the infant's head and the infant was lying on its stomach for 2 hours with the head turned to one side and in the normal and routine position in the nest in proportion to the body. His brain tape was recorded during these 2 hours

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences، Omolbanin hospital,

Full name of responsible person

Sedigheh Khanjari

Street address

Nursing Care Research center, Building of Nursing and Midwifery in front of Khatam Al-Nabia Hospital, Rashid Yasemi Ave. Above Vanak Sq, Valiasr Ave.,Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Sedigheh khanjari

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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
-Will be done upon request
When the data will become available and for how long
August 2020
To whom data/document is available
Research team
Under which criteria data/document could be used
Better care than premature baby
From where data/document is obtainable
Nursing Care Research Center
What processes are involved for a request to access data/document
Send a request to the head of the Nursing Care Research Center
Comments
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