

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

En Assessment of Effectiveness Of Clustering Care on Sleep Behaviors of Premature Neonates Hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim

Determining and comparing the mean score of neonatal sleep in the control group before and after routine interventions 2- Determination and comparison of the average score of neonatal sleep in the intervention group before and after the cluster care 3. Comparison of the mean score of neonatal sleep in the control and intervention groups

Design

The population of this study is all preterm infants admitted to Arash Hospital. The number of samples is 30, 15 of whom will be the control group of 15 in the intervention group. Selection of samples will be available and each participant will be given a specific one.

Settings and conduct

The researcher explores the case studies only in a research entitled The Effect of Clustering on the Sleep Behavior of Premature Babies in a Shift in the Morning and by a Nursing Constant in the Neonatal Intensive Care Unit of Arash Hospital. The beginning of the study will be from the beginning of the shift to the end of the shift. In the morning shift from 7 to 13, a newborn in the control group. Conventional care for the newborn in the intervention group. Cluster care (including all non-invasive measures such as feeding, changing position, weighing, changing props, size Getting round the head, giving medications ... and taking one of the aggressive actions such as replacing the veins, taking blood or suckling the baby). Immediately after feeding, based on the evolutionary behaviors of the infant (such as limb movement, facial swelling, crying ...), for 45 minutes, the baby's sleep behaviors are observed by the researcher or by the trained researcher. Will take. In each shift, two sleep cycles will be monitored and behaviors will be recorded every two minutes by the utility tool.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: fetal age from 30 to 37 weeks, minimum weight of 1000 grams, absence of abnormalities in the body, absence of prohibition of

position change, having a seizure order and conditions for withdrawal from septicemia and intolerance in each of the stages of the study

Intervention groups

Control group: After receiving consent from the parents, the baby received the usual care of the department. During the whole shift of the morning, two infant sleep cycles each one was observed and recorded for 45 minutes of sleep behaviors of the newborns in the relevant questionnaire. Group Intervention: After receiving parental consent, the baby is receiving clustering and categorized care. During a full shift in the morning, two infant sleep cycles each observed and examined for 45 minutes of neonatal sleep behaviors. The registration is placed in the relevant questionnaire. There is no intervention on the baby throughout the study period.

Main outcome variables

Improvement of sleep in newborns results in more weight gain, shorter hospitalization time, and improved arterial oxygen levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171021036909N1**

Registration date: **2017-12-25, 1396/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-25, 1396/10/04**

Update count: **0**

Registration date

2017-12-25, 1396/10/04

Registrant information

Name

batool pouraboli

Name of organization / entity

Country

Iran (Islamic Republic of)	Not used
Phone +98 21 6105 4413	Assignment Single
Email address b-pouraboli@sina.tums.ac.ir	Other design features
Recruitment status Recruitment complete	Secondary Ids empty
Funding source Tehran University of Medical Sciences	Ethics committees
Expected recruitment start date 2017-11-22, 1396/09/01	1
Expected recruitment end date 2018-02-18, 1396/11/29	Ethics committee
Actual recruitment start date empty	Name of ethics committee Ethics committee of Tehran University of Medical Sciences
Actual recruitment end date empty	Street address College Nursing and Midwife Street West Nosrat Squire Tohid
Trial completion date empty	City Tehran
Scientific title En Assessment of Effectiveness Of Clustering Care on Sleep Behaviors of Premature Neonates Hospitalized in Neonatal Intensive Care Unit	Province Tehran
Public title En Assessment of Effectiveness Of Clustering Care on Sleep Behaviors of Premature Neonates Hospitalized in Neonatal Intensive Care Unit	Postal code 1419733171
Purpose Supportive	Approval date 2017-09-27, 1396/07/05
Inclusion/Exclusion criteria Inclusion criteria: En Inclusion criteria: gestational age of 30-37 week At least 1000 grams weight Not having abnormalities at birth Not having a position change Having the command of gavage No use of sedative in the last 24 hours Not having seizures and taking anticonvulsants Dont consumption opiod by mother during pregnancy Exclusion criteria: Exclusion criteria:Toxic septicemia Intra ventricular hemorrhage grade III and IV Intolerance at each stage of the study	Ethics committee reference number IR.TUMS.FNM.REC.1396.3590
Age From 210 days old to 259 days old	Health conditions studied
Gender Both	1
Phase N/A	Description of health condition studied Preterm Infants' Sleep
Groups that have been masked <i>No information</i>	ICD-10 code P07
Sample size Target sample size: 30	ICD-10 code description Disorders related to short gestation and low birth weight, not elsewhere classified
Randomization (investigator's opinion) Not randomized	Primary outcomes
Randomization description	1
Blinding (investigator's opinion) Not blinded	Description Neonate Sleep Behaviors
Blinding description	Timepoint After feeding
Placebo	Method of measurement Questionnaire
	Secondary outcomes
	1
	Description Physiological signs of the neonate
	Timepoint

During the study period
Method of measurement
Prchatl questionnaire

Intervention groups

1

Description

In the control group, after getting permission from parent and general care, the sleep behaviors of neonates will be record by Perchtl after nutrition every 2 minute for 45 minute. Two cycle of sleep will be evaluated in every shift.

Category

Rehabilitation

2

Description

On the other hand, in the intervention group, the care will be done as clustered manner after getting permission from parent. Clustered care means doing several nursing care (including: changing position, changing probe location, giving medicine, weight,

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Marjan Bazrgari

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Corner 126 Kalantary, Shahid Baghbaniyan Ave.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Marjan Bazrgari

Position

Graduate Student in NICU Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marjan Bazrgari

Position

Master student of Neonatal Care

Latest degree

Bachelor