Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Study Parent Participation Care in neurobehavioral development of preterm infants in the neonatal intensive care unit

Protocol summary

Study aim
Study parent participation care in neurobehavioral development of premature infants in the neonatal intensive care unit

Design
A clinical trial with blinded the analyzer, with parallel group design of 186 premature infants, randomized, random allocation using Excel software.

Settings and conduct
1. Hazrat Rassol hospital, Neonatal intensive care unit 2. Vali-e-Asr hospital, Neonatal intensive care unit.

Participants/Inclusion and exclusion criteria
- Premature babies - Infant age ≤32 weeks with ≤1500 grams - Stable physiological state (pulse, respiration, oxygen saturation) and temperature - No need for mechanical ventilation - Mothers and fathers of premature infants should not take neuroleptic drugs and opioid - Parents live together Exclusion criteria: - Dissatisfaction of parents for any reason - The possibility of brain abnormalities and other physical abnormalities as well as other problems such as: - Intraventricular bleeding and necrotizing enterocolitis - Continuous instability of physiological conditions (pulse, respiration and oxygen saturation of blood) - The possibility of infant death in the first days of life

Intervention groups
- Intervention group receive unlimited time parents holding (held in arms and skin-to-skin care) - Control group receive routine care - Duration held skin-to skin will investigated on neurobehavioral outcome and compared with control group.

Main outcome variables
Neuromuscular development: 1. including joints, wrists, elbows, shoulders, ankles, knees, and thighs 2. Sucking and breastfeeding

General information

Reason for update

Acronym
PPC

IRCT registration information
IRCT registration number: **IRCT20140604017972N14**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-10-26, 1400/08/04**
Update count: **1**

Registration date
2021-05-18, 1400/02/28

Registrant information

Name
Zahra Godarzi

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

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-20, 1400/03/30

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study Parent Participation Care in neurobehavioral development of preterm infants in the neonatal intensive care unit

Public title
The effect of parent participation care on premature infants neurobehavioral development
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
- Parents signed informed consent. - Singleton born premature infants ≤ 32 weeks - weighing less than <1500g gestational age - enrolled the first born in 3-7 days of life. - Mothers should not take any psychiatric medication and any drug abuse - fathers should not take any psychiatric medication and any drug abuse - Parents live together.
Exclusion criteria:
- without any: - congenital physical and cerebral seizure - Intraventricular and Intracerebral hemorrhage - Persistent instability of physiological conditions (pulse respiration and oxygen saturation of blood). - necrotizing enterocolitis. -Those infants expected to expire within the first days of life were excluded.
Age
From **180 days** old to **280 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **186**
More than 1 sample in each individual
Number of samples in each individual: **2**
- One person: gets parental care: hug and hug skin to skin (kangaroo care) - One person in control: gets routine care
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation is made for each newborn as a randomization unit and by a randomized balanced block method (without stratification) is done with a predetermined block size. Using excel software, which assigns each baby to two groups, with sequential numbers and attached to their forms in opaque sealed envelopes. This is done by one of our colleagues who is not involved in the study and hided the randomization list until the statistical analysis
Blinding (investigator's opinion)
Single blinded
Blinding description
- The parents and their infants are directly involved as executor and the control group don’t receive any intervention, can't be blinded them. - Regarding the researcher who is as the executor of the study in the field, and teach parents how to perform the intervention and follow the consequences and examinations, can't be blinded any of them. - The only person who kept concealed is the data analyzer, he will analyzed groups named A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
https://ethics.research.payamnoor.ac.ir
Street address
No. 26, Soleimani Ave., Hedayati (kerman shomali) Noamoz Street..
City
Tehran
Postal code
1675784514
Approval date
2021-01-26, 1399/11/07
Ethics committee reference number
IR.PNU.REC.1399.154

Health conditions studied

1

Description of health condition studied
1. Born at preterm 2. Low birth weight
ICD-10 code
P07
ICD-10 code description
Disorders of newborn related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description
1. Heart rate
Timepoint
1. Before, during and after intervention
Method of measurement
1. pulse oximeter monitoring device

2

Description
2. Respiration rate
Timepoint
2. Before, during and after intervention
Method of measurement

2. pulse oximeter monitoring device

3

Description
3. oxygen saturation level
Timepoint
3. Before, during and after intervention
Method of measurement
3. pulse oximeter monitoring device

4

Description
4. Behavioral responses
Timepoint
4. Before, during and after intervention
Method of measurement
4. The Neonatal Behavioral Assessment Scale

5

Description
5. Indicators of neuromotoral function
Timepoint
5. at 35 and 40 weeks of age
Method of measurement
5. The Test of Infant Motor Performance (TIMP)

Secondary outcomes

1

Description
1. Neurobehavioral development
Timepoint
1. At the age of ≤32 weeks 2. At the age of 35 weeks 3. At the age of 40 weeks
Method of measurement
1. Dubowitz Scale: To assessment neurological, physical criteria and to determine gestational age at birth. 2. TIMP: Is a motor outcome to assess the posture and selective control of movement needed by infants for functional performance in daily life. 3. TIMP: Is a motor outcome to assess the posture and selective control of movement needed by infants for functional performance in daily life.

Intervention groups

1

Description
186 hospitalized premature infants' ≤32 weeks of gestation are included in the study on days 3 to 7 after birth without congenital anomalies or serious problems and lack of chance of death. After announcing the informed consent of the parents and the random assignment of the infants in the "intervention group" and the "control group"; Examinations and clinical evaluation to determine fetal age will performed with Dubowitz instrument in "both groups" after physician approval for "intervention group", parents will be given sufficient training on how to hug and hug skin to skin (kangaroo care). The presence of parents in the nicu with no time limit for any type of cuddling (hugging or kangaroo care) and its effectiveness on behavioral neurodevelopment at 34 and 40 weeks of age equivalent to the postnatal semester age is assessed by TIMP. The control group receiving "routine care" is compared.
Category
Prevention

2

Description
Control group: take nicu routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rassol hospital, NICU
Full name of responsible person
Dr Prissa Mohagg
Street address
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
payam noor university
Full name of responsible person
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Web page address
http://www.pnu.ac.ir

Grant name
Payame Noor University
Grant code / Reference number
دانشگاه پیام نور
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
payam noor university
Proportion provided by this source
100
Public or private sector
Private
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
payam noor university
Full name of responsible person
Zahra Godarzi
Position
Nursing Instructor of Pediatric and Neonatal Intensive Care Unit
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Other areas of specialty/work
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Person responsible for updating data

Contact
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payam noor university
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Zara Godarzi
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
1- study tools and statistical data from the whole data
When the data will become available and for how long
6 months after end of study
To whom data/document is available
Neonatologists, Neonatal Intensive Care Nurses, Neonatal Occupational Therapists
Under which criteria data/document could be used
The family-centered Interventions in the intensive care units favored the overall neurobehavioral performance in VLBW preterm infants at term age.
From where data/document is obtainable
Zahra Godarzi godarziz@tums.ac.ir Tell: 00989122072918
What processes are involved for a request to access data/document
By Email is the best way to have contact in short time
Comments