

# 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  $\leq 32$  weeks with  $\leq 1500$  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)

###### Phone

+98 21 6105 4407

###### Email address

godarziz@tums.ac.ir

##### 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  $\leq$  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 hid 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  $\leq 32$  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'  $\leq 32$  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**

1- Hazrat Rassol hospital, Sattar khan St, Niayesh St, Mansouri Ave.

##### **City**

Tehran

##### **Postal code**

1449614535

##### **Phone**

+49 2164 351000

##### **Email**

pmohagh@yahoo.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Vali-e-Asr hospital, NICU

##### **Full name of responsible person**

Dr ziba Mosaybi

##### **Street address**

Vali-e-Asr hospital, NICU.,Keshavarz Blvd. Gharib St.

##### **City**

Tehran

##### **Postal code**

۱۴۱۹۷۳۳۱۴۱

##### **Phone**

+49 2161 192359

##### **Email**

mosayebiir@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

payam noor university

**Full name of responsible person**

Dr Mahnaz Aliakbari

**Street address**

Nakhl Street, Artesh Highway, Mini City, central organization, Payame Noor University Tehran

**City**

Teharan

**Postal code**

43183-14556

**Phone**

+49 9122 234260

**Fax****Email**

int@pnu.ac.ir

**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

**Latest degree**

Master

**Other areas of specialty/work**

Neonatal Intensive Care units

**Street address**

No. 26, Soleimani Ave., hedayati (kerman shomali) noamoz street.

**City**

Tehran

**Province**

Tehran

**Postal code**

1675784514

**Phone**

+98 21 2250 7961

**Email**

godarziz@tums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Parissa Mohagg

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neonantologist

**Street address**

Satarkhan Av, Niayesh St, Hazrate Rasool Akram Hospital,

**City**

Tehran

**Province**

Teharan

**Postal code**

1449614535

**Phone**

009822507961

**Email**

pmohagh@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

payam noor university

**Full name of responsible person**

Zara Godarzi

**Position**

Nursing Instructor in pediatric and neonatal intensive care unit

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No. 26, Soleimani Ave., hedayati (kerman shomali) noamoz st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1675784514

**Phone**

+98 21 2250 7061

**Email**

godarziz@tums.ac.ir

## 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