

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of nesting position on stress motor behaviors in preterm infants

#### Protocol summary

##### Summary

The Aim of this research, is the effect of nesting position on stress motor behaviors in preterm infants in the Neonatal Intensive Care Unit. This clinical trial is not blinded. By balanced blocked randomization, infants are put into control or intervention groups. Total of 44 stable preterm infants hospitalized in Neonatal Intensive Care Unit (NICU) in Hazrate Rasool hospital of Tehran University of Medical Science participate in the trial. Their gestational age is 30 weeks to 33 weeks 6 day, with birth weight between 1000 to 1500 gr. And without need to mechanical ventilation or prescription Phenobarbital or phenytoin till the end of the program. Intervention is putting the experimental infants in to the nest for one week. After taking informed consent from parents, the first day, they are filmed for 20 minutes without interruptions, when they rest in the incubator in prone position. Experimental group are put into the nest for seven days. The control group rest into the incubator without nest. After seven days they will be videotaped again. Total of stress motor behaviors will be counted in both groups, before and 7 days later. It is predictable that nesting position may reduce stress motor behaviors.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111298251N1**

Registration date: **2012-07-25, 1391/05/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-25, 1391/05/04

##### Registrant information

##### Name

Zahra Eskandari

##### Name of organization / entity

Tehran Nursing and Midwifery Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6692 7171

##### Email address

z-eskandari@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

NICU Master Thesis, with Nursing Research Center of Tehran University of Medical Science support

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2012-09-20, 1391/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of nesting position on stress motor behaviors in preterm infants

##### Public title

Effect of nesting position on stress

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Birth weight:1000-1500 gr.; Gestational age at birth of 30 weeks to 33 weeks 6 days(<34weeks) after mother's last menstrual period; Being in secondary week postnatal age; Resting into the incubator; absence of congenital or chromosomal abnormality, IUGR, or other anomalies like clavicle fracture, hip or limb deformities. exclusion criteria: substance abuse in mothers; Intra ventricular hemorrhage(3 ,4 degree)that

recognized by brain ultrasound; Sepsis; NPO, any invasive ventilation, prescription Phenobarbital or phenytoin till end of the program.

#### **Age**

To **1 year** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **44**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical Science

##### **Street address**

Research Center, Ghods Ave, Keshavarz Blvd

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2012-06-09, 1391/03/20

#### **Ethics committee reference number**

55123

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Stress

#### **ICD-10 code**

F43, F43.0

#### **ICD-10 code description**

F43:Reaction to severe stress, and adjustment disorders-  
F43.0 :Acute stress reaction

### **Primary outcomes**

#### **1**

#### **Description**

Total stress motor behaviors

#### **Timepoint**

Before intervention, One week after intervention

#### **Method of measurement**

Als's behavior observation(standard)

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

#### **Description**

In evening shift of first day and before nesting position, the researcher videotapes behaviors for 20 minutes continued. Through recording, infant is in the incubator in prone position just with a diaper and small pad under the shoulder. The researcher records infants' posture and movements. Experimental group are put into the nest for seven days. Nests are oval shaped cloth with boundaries in both sides that also surrounds feet. It's size is chosen according to the infants weight. The positioning program through nesting will be taught to the nurses. Throughout this period, the infant can remove from the nest, for weighting, breastfeeding, bathing and other cares. After seven days nest is removed and 20 minutes recording of infants will be done, in such before. The researcher review the films for count and comparing total stress motor behaviors.

#### **Category**

Other

#### **2**

#### **Description**

In the control group, in the evening shift of first day, the researcher videotapes behaviors for 20 minutes continued. Through recording, infant has laid in the incubator in prone position and dressed in a diaper with small pad under the shoulder. The researcher records infants' posture and movements. One week later, they will be filmed in such before. In these seven days he/she will gain routine nursing cares. The researcher review the films for count and comparing total stress motor behaviors. The researcher review the films for count and comparing total stress motor behaviors.

#### **Category**

Other

### **Recruitment centers**

#### **1**

#### **Recruitment center**

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

Hazrate Rasool Teaching Hospital

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

Dr. Parisa Mohagheghi

**Street address**

Satar khan Ave, Tehran

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Fateme Banazade

**Street address**

Research Center, Pursina Bldg, Ghods Ave, Keshavarz Blvd

**City**

Tehran

**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 Science

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran Nursing and Midwifery Faculty

**Full name of responsible person**

Zahra Eskandari

**Position**

Master Student in NICU

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Tehran Nursing and Midwifery Faculty

**Full name of responsible person**

Dr Naima Seyedfatemi, Dr Parisa Mohagheghi, Dr. Heidelise Als

**Position**

PHD, Neonatologist, PHD

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty*

