

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)

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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

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

Tehran University of Medical Science

Full name of responsible person

Fateme Banazade

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Research Center, Pursina Bldg, Ghods Ave, Keshavarz Blvd

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

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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Tehran Nursing and Midwifery Faculty

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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

