

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of neuro-developmental status of preterm neonates with and without family based interventions

Protocol summary

Summary

Objectives: effects of family based intervention on the neurodevelopmental status of preterm neonates. Study design: Based on parents' consent, some preterm neonates entered as intervention group and some preterm neonates without any intervention entered as the control group. Inclusion and exclusion criteria: Preterm birth (gestational age < 35 weeks) and NICU hospitalizations as inclusion and congenital anomaly was considered as exclusion criteria. Sample size: 50 neonates in each group. Intervention: Training sessions for mothers to stimulate skin, hearing and sight senses of neonates daily, performance massage and hydrotherapy and playing with them. Time of intervention: Training sessions were held every 2 months till 12 months. primary outcome: Assessment of the family based interventions on the neurodevelopmental status of preterm neonates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705079568N17**
Registration date: **2017-10-02, 1396/07/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Maternal, Fetal and Neonatal Research Center, Tehran
University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of neuro-developmental status of preterm neonates with and without family based interventions

Public title

Influence of family based intervention on neuro-developmental status of preterm neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Preterm birth (gestational age < 35 weeks) and NICU hospitalization. Exclusion criteria: Congenital anomaly.

Age

To **1 year old**

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not 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

Ethics committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 6th floor of Tehran University of Medical Sciences, Ghods St., Keshavarz blv, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-03-20, 1391/01/01

Ethics committee reference number

1097

Health conditions studied

1

Description of health condition studied

preterm neonates

ICD-10 code

P07

ICD-10 code description

Disorders related to short gestation and low birth weight

Primary outcomes

1

Description

Neuro-developmental status of neonates

Timepoint

At birth and after 12 months

Method of measurement

Age & Stage Questionnaire (ASQ) and Gesell Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Parents' training sessions were held every 2 months for an hour. They should stimulate the skin of their children by massage, stimulate hearing sense by singing and whispering and vision stimulation by colorful cards and toys, hydrotherapy and playing with neonates daily for 45 minutes.

Category

Prevention

2

Description

Neonates in the control group will not receive any special intervention except from routine visits.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU, Vali-e-Asr Hospital

Full name of responsible person

Zahra Farahani

Street address

Maternal Fetal and Neonatal research center, Vali-e-Asr Hospital, Imama Khomeini Hospital, Bagher Khan Ave., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maternal fetal neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street address

Vali-Asr Hospital, Imam Khomeini Hospital, Bagher Khan Ave., Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Maternal fetal neonatal Reseach Center, Tehran
University of Medical Sciences

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**

Maternal Fetal and Neonatal Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Zahra Farahani

Position

Physiologist, Researcher

Other areas of specialty/work**Street address**

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Professor

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Maternal Fetal and Neonatal Research Center

Full name of responsible person

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PhD Candidate in Physiology

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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

Data Dictionary

empty