

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of tactile-kinesthetic stimulations through mother on physical development, reflex state and motor development in preterm neonates of neonatal unit

Protocol summary

Summary

The aim of this study was to investigate the effect of tactile kinetic stimulation on physical development, reflex state and motor development in preterm neonates. So, among all of the preterm neonates of Amiralmomenin hospital neonatal unit of Semnan city, 40 neonates and their mothers selected purposefully and randomly divided to experimental and control groups. Then, mothers of experimental group conducted tactile kinetic stimulation on neonates to completion of fetal period (40 weeks gestation) for 20 minutes and three times a day whereas, control group received only usual care. The results showed tactile kinetic stimulation led to significant improvement in physical development of experimental group compared to the control group. Moreover, reflex state of the neonates in both groups there was no significant difference. While, motor development of neonates in the experimental group at end of intervention and after 4 months, significantly better than the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012318945N4**

Registration date: **2017-03-11, 1395/12/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-11, 1395/12/21

Registrant information

Name

Mansoureh Mokaberian

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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+98 23 3345 5399

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tactile-kinesthetic stimulations through mother on physical development, reflex state and motor development in preterm neonates of neonatal unit

Public title

The effect of massage on physical development, reflex state and motor development in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a Persian race; not admitted to neonatal intensive care unit during the investigation; there was no history of genetic disease; psychiatric and addiction in the mother; gestational age 32- 37 weeks

and Apgar score in first and fifth minutes later than 7 in neonates. Exclusion criteria: the need for medical interventions on neonates; the incidence of symptoms of skin disease and infectious disease in neonates; unstable and irregular heart rate; do not touch techniques work for at least two consecutive times and unwillingness to continue cooperation.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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**

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd, Semnan

City

Semnan

Postal code**Approval date**

2014-12-02, 1393/09/11

Ethics committee reference number

2889

Health conditions studied**1****Description of health condition studied**

preterm neonate

ICD-10 code

060

ICD-10 code description

Preterm delivery without spontaneous labour

Primary outcomes**1****Description**

Physical development

Timepoint

Before intervention and after completion of fetal period (40 weeks gestation)

Method of measurement

Antropometric measures

2**Description**

Rerlex

Timepoint

Before intervention and after completion of fetal period (40 weeks gestation)

Method of measurement

Brazelton test

3**Description**

Motor development

Timepoint

After completion of fetal period (40 weeks gestation) and 4 months after intervention

Method of measurement

Peobody test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: phase 1 and 3: tactile stimulation; phase 2: kinetic stimulation

Category

Treatment - Other

2**Description**

Control group: Receiving usual care

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin Hospital of Semnan

Full name of responsible person

Mansoureh Mokaberian

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MostafaKhomeini Blvd, Semnan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Sciences
Full name of responsible person
Dr. Rashidipoor
Street address
Basij Blvd, Semnan
City
Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Semnan 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

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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