

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of tactile stimulation of movement by the mother's physical growth of premature infants

Protocol summary

Study aim

This study is aimed to evaluate the efficacy of tactile stimulation by mother on growth indices in premature neonates.

Design

This clinical trial will be controlled with a parallel group and randomized. Hundred hospitalized premature infants (50 infant in each groups) will be enrolled in this study. participants will be randomized in blocks of 4.

Settings and conduct

This study will be conducted in neonatal and NICU wards of two major hospitals in Mazandaran province (Imam Sajjad Hospital of Ramsar and Shahid Rajjai of Tonekabon). In the beginning of enrollment demographic and clinical data are recorded. Also, throughout the trial respiratory rate, pulse rate, calorie intake and growth indices are recorded in intervals. The 15 minutes massage (tactile stimulation) are divided in 3 five minutes intervals. In first and last phase, neonate is placed in prone position and touched gently with finger pulp of both hands, five determined areas are touched for one minute. In the middle phase, the infant is positioned supine and 6 passive extension-flexion movements (one every 10 seconds) are given in the following five areas: right arm, left arm, right foot, left foot and both legs. The intervention will be performed between 7 a.m and 7 p.m

Participants/Inclusion and exclusion criteria

Neonatal age of 5 Gestational age of less than 37 weeks
Absence of any congenital anomalies
Absence of maternal addiction to alcohol, cigarette and illicit drug
Absence of any surgical intervention in neonate
Absence of feeding anything other than exclusive breast-milk

Intervention groups

In this group, neonates will receive tactile stimulation by their mothers other than standard care. Tactile stimulation will be performed in three separate episodes of 15 minutes during three hours. This regimen is continued for ten consecutive days.

Main outcome variables

Growth parameters in month 1, 2 and 3 after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046027N1**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **prospective**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

ali siahposht-khachaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4051

Email address

a.siahposht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of tactile stimulation of movement by the mother's physical growth of premature infants

Public title
Effect of Touch Therapy on Infant Growth

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
More than 5 days of age gestational age < 37 weeks
Birth weight between 1000 to 1500 grams Exclusive breast feeding
Exclusion criteria:
Congenital anomalies Mother with alcohol, cigarette or drug addiction Prior history of surgery

Age
From **5 days** old to **5 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Neonates are allocated in blocks of 4. Blocks are created by sealed envelope website.

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 mazandaran University of Medical Sciences

Street address

No. 20, Taleghani Ave.

City

Ramsar

Province

Mazandaran

Postal code

4691786953

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.MAZUMS.REC.1395.2681

Health conditions studied

1

Description of health condition studied

Prematurity

ICD-10 code

P05

ICD-10 code description

Disorders of newborn related to slow fetal growth and fetal malnutrition

Primary outcomes

1

Description

Head Circumference

Timepoint

at birth, before intervention and 1, 2, 3 month after intervention

Method of measurement

Measuring tape

2

Description

Height

Timepoint

at birth, before intervention and 1, 2, 3 month after intervention

Method of measurement

Measuring tape

3

Description

Weight

Timepoint

at birth, before intervention and 1, 2, 3 month after intervention

Method of measurement

Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neonates in this group will receive 45 minutes daily massage in addition to standard care. The

45 minutes massage is delivered in three 15 minutes episodes for ten days. The 15 minutes massage are divided into three 5 minutes intervals. In the first and last phase, the neonate is placed in the prone position and touched with finger pulps of both hands. The following five areas are touched every minute: Twelve touch movements (one every 5 seconds) from the tip of the head downward to the face, neck and vice versa. Twelve touch movements (one every 5 seconds) from the back of the neck across the shoulders and vice versa. Twelve Touch movement (one every 5 seconds) from the upper back to the lower back and vice versa. Twelve Touch movement (one every 5 seconds) from the thighs down to the ankle and vice versa. Twelve touch movement (one every 5 seconds) from shoulder to wrist and vice versa. In the middle phase, the neonate is placed in the supine position and six passive extension-flexion movements (one every 10 seconds) are given in the following five areas: Right and left arms, Right foot and left legs, and both feet. The intervention will be performed between 7 a.m and 7 p.m.

Category

Treatment - Other

2**Description**

Control group: Control group neonates will receive regular care of the ward.

Category

Treatment - Other

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

Imam Sajjad Hospital

Full name of responsible person

Hossein Firouzi

Street address

Shahrdari Sq, Imam Sajjad Hospital

City

Ramsar

Province

Mazandaran

Postal code

46917-14144

Phone

+98 11 5522 2033

Email

firoozihosein@mazums.ac.ir

2**Recruitment center****Name of recruitment center**

Shahid Rajjai Hospital

Full name of responsible person

Hossein Firouzi

Street address

Imam Khomeini St, Shahid Rajjai Hospital

City

Tonekabon

Province

Mazandaran

Postal code

4681648183

Phone

+98 11 5423 7001

Email

firoozihosein@mazums.ac.ir

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

Mazandaran University of Medical Sciences

Full name of responsible person

Davood Farzin

Street address

Taleghani Ave, No. 20

City

Ramsar

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 5522 6108

Email

davoodfarzin@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Mazandaran University of Medical Sciences

Full name of responsible person

Hossein

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Taleghani Ave, No.20

City

Ramsar

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 5522 6108

Email

firoozi.hosein@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hossein

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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4815733971

Phone

+98 11 5522 6108

Email

firoozi.hosein@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Siahposht-khachaki

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Valie-Asr Boulevard, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4051

Fax

+98 11 3322 1626

Email

a.siahposht@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all collected deidentified data for primary and secondary outcome measures are going to be shared

When the data will become available and for how long

After publishing the study, data are going to be available

To whom data/document is available

Data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

Permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

Requests are gathered through principle researcher's e-mail address

What processes are involved for a request to access data/document

Upon verification of request and reason data are given in three month.

Comments