Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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 sealedenvelope 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

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 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