

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Study of the effect of Tactile-kinesthetic stimulations on neonatal behaviors and physical growth in LBW neonates hospitalized in NICU

Protocol summary

Summary

This study was designed to fine out the effects of tactile stimulation on physical growth and neonatal behavior in low birth weight neonates. This is a Randomized Controlled Trial (RCT) study type that is single blind and without placebo. The study is carried out on LBW neonates in Akbar-abadi hospital of Tehran. The study sample is made out of 40 inborn LBW neonates, who selected simple randomly and divided into control and treatment groups base on stratified. Inclusion criteria included: hospitalized in NICU of Akbar abadi hospital; Birth weight (BW) >1500 g and <2499g ; Medically stable with no requirement of drugs (other than mineral and vitamin supplements), or any specific interventions (with doctor diagnosis) ; Absence of congenital anomalies and neuromuscular disorders (with doctor diagnosis); parents should fill inform consent exclusion criteria: neonates who their parents tend to excluded their neonates of the study for any reason and any time; if acute physical problems occur during the study, newborn is removed from the sample. A questionnaire containing information on the general profile of the neonate and neonatal and infancy records to be completed with question of parents and study of medical records by researcher and after Completing the questionnaire, neuro-behavioral examination to check the status of behavioral and developmental of neonates and assessment of physical growth are done for both groups and the results will be recorded. in the next step, according to a specific protocol, intervention (including the tactile stimulation and passive movements of limbs) is done for the treatment group for 10 days and the results of re-evaluation are compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105016352N1**

Registration date: **2012-02-25, 1390/12/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-25, 1390/12/06

Registrant information

Name

Faranak Aliabadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Tactile-kinesthetic stimulations on neonatal behaviors and physical growth in LBW neonates hospitalized in NICU

Public title

Study of the effect of Tactile-kinesthetic stimulations on neonatal behaviors and physical growth in LBW neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: : hospitalized in NICU of Akbar abadi hospital; Birth weight (BW) >1500 g and <2499g ; Medically stable with no requirement of drugs (other than mineral and vitamin supplements), or any specific interventions (with doctor diagnosis) ; Absence of congenital anomalies and neuromuscular disorders (with doctor diagnosis) ; parents should fill inform consent
Exclusion criteria: neonates who their parents tend to excluded their neonates of the study for any reason and any time; if acute physical problems occur during the study newborn is removed from the sample

Age

To **1 year** old

Gender

Both

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)

Single 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

Tehran University of Medical Science-Enghelab square-Tehran-Iran

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

90/ 260/520/ ۵

Health conditions studied

1

Description of health condition studied

low birth weight neonates

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight

Primary outcomes

1

Description

weight

Timepoint

at the first and tenth days

Method of measurement

digital scale(gram)

2

Description

infant's behaviors

Timepoint

at the first and tenth days

Method of measurement

Brazelton scale

Secondary outcomes

empty

Intervention groups

1

Description

The massage therapy protocol is done for treatment group for 10 days. massage therapy is begun on the first day of birth and continue for 10 consecutive days. The massage sessions comprised three segments which is two five-minute phases of tactile stimulation and one five-minute phase of kinesthetic stimulation that is given during the middle phase. During tactile stimulation, the neonate is placed in prone position and stroked with the fingers of both hands of therapist for 5, one- minute periods over each region in the following sequence: 1) from the top of the head to the neck , 2) from the neck across the shoulders and back to the neck, 3) from the upper back to the buttocks and revert to the upper back, 4) from the thigh to the foot to the thigh on both legs simultaneously, and 5) from the shoulder to the hand to the shoulder on both arms simultaneously. For the kinesthetic phase, neonate is placed in supine position. This phase consist of six passive flexion/extension movements lasting approximately 10 seconds each. These movements occur in the following sequence: 1) right arm, 2) left arm, 3) right leg, 4) left leg, and 5) both leg simultaneously. Finally tactile stimulation is repeated

in third phase.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbar Abadi Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Shadmehr

Street address

Rehabilitation School, Shahnazari Ave, Mohseni

Square, Mirdamad, 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

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

Tehran University of Medical sciences

Full name of responsible person

Faranak Aliabadi

Position

faculty member of Tehran University of Medical Sciences

Other areas of specialty/work

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Reihaneh Askary

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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