

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison the effect of Physical Activity Programs on Physiological and Behavioral Responses, Motor Performance and Neuromuscular Development in preterm Infants: Single blind Randomized Clinical Trial

Protocol summary

Summary

This study is a single blind clinical trial in order to compare the effect of physical activity programs on physiological and behavioral responses, motor performance and neuromuscular development in preterm infants. A population of preterm neonates with 26-30 weeks of gestational age and birth weight at least 800 g admitted to the medical center Alzahra of Tabriz, is studied. The present study will do during the 32 weeks. Sample size will be 72 persons. Infants will be randomly divided to 4 groups: Physiotherapy, Hydrotherapy, Combination and Holding (Containment). The program duration is 14 days. The physical activity program's→ was based on the Meyer-Miller protocol. Briefly, this protocol involves extension and flexion, range of motion exercise with passive resistance of both the upper and lower extremities (total 12 sessions). On every week will be considered a day of rest. In the hydrotherapy group, the researcher will be done semi-circular movements in the pelvic area while the head and neck will constant and then semi-circular motions will performed in the head and neck while the pelvis will be constant. Each session will be 10 minutes and carried out 7 sessions every other day. Combination group, every other day will be done physiotherapy and hydrotherapy. In Holding group, the researcher will be kept baby for at least 15 minutes daily once on fetus state (hands in the mid-line and legs tucked on the abdomen). Physiological and behavioral responses of infants will be measured during and 10 minutes before and after the interventions. Infant's behavioral responses will be evaluated by the Neonatal Individual Development Care and Assessment Program group analyzers. Motor performance by Test of infant motor performance and neuromuscular evolution evaluate with selected items from the Dubowitz and NEW BALLAR scales.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405208315N7**

Registration date: **2014-08-25, 1393/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-25, 1393/06/03

Registrant information

Name

Leila Valizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-08-16, 1393/05/25

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Physical Activity Programs on Physiological and Behavioral Responses, Motor Performance and Neuromuscular Development in preterm Infants: Single blind Randomized Clinical Trial

Public title

The effect of physical activity on Physiological and Behavioral Responses, Motor performance and Neuro-muscular Development

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Gestational age 26-30 weeks; Post conception age 32 weeks; Birth weight at least 800 gram; Weight the studying time 1000-2000 gr; Appropriate Gestational age; APGAR scores more than 7; Mother has not drug abuse; Infant isn't IUGR; Infant has a Positive history of mechanical ventilation(Mechanical ventilation, CPAP, Oxyhood) at least for 3 days and use of sedative drug; Infant has not any medicine and metabolic disorders; Absence of neurological anomalies, congenital and chromosomal abnormalities. Exclusion Criteria: Delayed diagnosis of neural anomalies, Congenital and chromosomal abnormalities at 32 to 34 weeks; Severe infection and diseases require to surgery and photo-therapy at 32 to 34 weeks; Physiological instability during the program, as HR more than 180 or HR less than 100 and SaO2 drops to less than 88% twice a day during the intervention (Particularly during the Hydrotherapy); Diagnosis the cardiovascular and musculoskeletal diseases, hip dislocation and Erb Duchenne paralysis during the study; Transfer to another facility during the intervention.

Age

From **7 days** old to **2 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Tabriz University of Medical Sciences

Street address

South Shariati Ave. Nursing and Midwifery Faculty

City

Tabriz

Postal code

5138947979

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

9360

Health conditions studied

1

Description of health condition studied

1-Preterm Infant 2- low birth weight

ICD-10 code

p07 ,p07.1

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified. 2-Other low birth weight

Primary outcomes

1

Description

Physiologic indexs(Heart rate, Respiration Rate, Saturation Oxygen).2- Behavioral responses

Timepoint

1- The two first and last sessions of intervention (before, during and after the intervention).

Method of measurement

1- Pulse oximetre set. 2- APIB: Assessment of Preterm Infant's Behavior

Secondary outcomes

1

Description

1-motor performance 2- neuromuscular developmental of Joint of Wrists, Elbows, Shoulders, Ankles, Knees, Thighs

Timepoint

1-Before the first session and after the last session of the intervention. 2-Before the first session and after the last session of the intervention.

Method of measurement

1- Test of Infant Motor Performance (TIMP) 2-Selected items from Neuromuscular maturity NEW Ballard and Dubowitz scales

Intervention groups

1

Description

1-The physical activity program will be based on the Moyer-Mileur protocol. Then repetitions of each movement were performed on the Wrists, Elbows, Shoulders, Ankles, Knees and Hips joints. The sequence was performed slowly and in the cephalocaudal direction, with an average of six movements per min, and in the following sequence: right arm, left arm, right leg, left leg and, finally, simultaneous movements on both legs.~ Intervention will be done for a total of 15 min. 2- Hydrotherapy activity will be done semi-circular movements in the pelvic area while the head and neck will constant and then semi-circular motions will performed in the head and neck while the pelvis will be constant. Intervention will be done for a total of 10 min. 3- Containment include putting the infant in fetal position (feet gathered on the abdomen and head bent the chest). Baby will be hold Daily once for 15 minutes.

Category

Rehabilitation

2

Description

Holding group's :The researcher will be kept baby in fetal position to support the head~, neck and extremities (the bent in the midline) for 15 min, once daily.

Category

Rehabilitation

3

Description

Hydrotherapy groups: semi rotational movements of the head and neck will be doing while pelvic area is constant and then semi rotational movements of the pelvic will be doing while the head and upper parts are constant , it will run during 10 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Therapeutic Center Al-Zahra

Full name of responsible person

Leila Valizadeh

Street address

Tabriz, South Artesh Street, Bagh Shomal Cross, Al Zahra Hospital

City

Tabriz

2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Leila Valizadeh

Street address

South Shariati Street- Nursing and Midwifery faculty

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Azadi Street, Golgasht Street, Tabriz University of Medical Sciences

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz nursing and midwifery faculty

Full name of responsible person

mahnaz sanaeifar

Position

Master Science Student of neonatal intensive care

Other areas of specialty/work

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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