Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

The effect of multi-sensory stimulation on the development of neuromuscular, weight and physiological parameters in preterm infants

Protocol summary

Summary

Preterm birth is the most common cause of death in babies and as one of the risk factors is intended for developmental disabilities Which can lead to long-term effects on the Neuromuscular development. Since the original development is done during pregnancy, especially during the last months and weeks and the babies are born too early, so had ample opportunity for the development of critical systems developmental and physiological problems may have multiple.Multi-sensory stimulation is relatively new intervention to simulate the environment in the first weeks of intrauterine life; to maintain and facilitate the development in premature infants.This study aimed to effect of multi-sensory stimulation on the development of neuromuscular, weight and physiological parameters in preterm infants.In this clinical trial, 80 preterm infants with gestational age between 32 and 36 weeks were assigned randomly into two groups and controlled multisensory stimulation.Groups intervention, multisensory stimulation program for 12 minutes a day, 5 times a week at a time until discharge and the control group received only usual care.Physiological parameters (respiration, heart rate, blood pressure and oxygen saturation) using the monitoring and the development of neuromuscula using the Infant Neurological International Battery before and after the intervention, as well as daily weight gain the researcher measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073114454N2**
Registration date: **2016-08-17, 1395/05/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-17, 1395/05/27

Registrant information

Name
Fatemeh Nasimi
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Jahrom University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-09-02, 1395/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multi-sensory stimulation on the development of neuromuscular, weight and physiological parameters in preterm infants

Public title

The effect of multi-sensory stimulation on the development of neuromuscular, weight and physiological parameters in preterm infants

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: parental consent; infants age between 37-30 weeks; hemodynamic stability (HR=120-160, RR=30-50, SPO2=85%-95% and keep axillary temperature range of 37-36 Centigrade degrees); Apgar scores of 7 or more on the first and fifth minutes of birth; spontaneous ventilation and no need for ventilation; lack of congenital malformations. Exclusion criteria: lack of consent to continue working for any reason; ventilation need during the study; infants with recurrent Apnea; seizures during the study.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jahrom University of Medical Sciences
Street address
Jahrom University of Medical Sciences, Motahari Street, Jahrom
City
Jahrom
Postal code
Approval date
2016-03-09, 1394/12/19
Ethics committee reference number
IR.JUMS.REC.1394.207

Health conditions studied

1

Description of health condition studied
Preterm infants
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Heart Rate
Timepoint
Before and after the intervention.
Method of measurement
with monitoring

2

Description
Blood Pressure
Timepoint
Before and after the intervention.
Method of measurement
with monitoring

3

Description
Oxygen Saturation
Timepoint
Before and after the intervention.
Method of measurement
with monitoring

4

Description
Respiration Rate
Timepoint
Before and after the intervention.
Method of measurement
with monitoring

Secondary outcomes

1

Description
Neuromuscular development
Timepoint
Before and after the intervention.
Method of measurement
Using tool Infant Neurological International Battery

2

Description
Weight gain
Timepoint

Daily

Method of measurement

Using the Balance

Intervention groups

1

Description

The intervention group receive multi-sensory stimulation for 12 minutes every day, 5 times a week until discharge

Category

Prevention

2

Description

The control group received usual care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Intensive Care Unit, Motahari Hospital

Full name of responsible person

Fatemeh Nasimi

Street address

Neonatal Intensive Care Unit, Motahari Hospital, Motahari Street, Jahrom

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Jahrom University of Medical Sciences

Full name of responsible person

Dr. Kavus Solhjo

Street address

Jahrom University of Medical Sciences, Motahari Street, Jahrom

City

Jahrom

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, Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Fatemeh Nasimi

Position

MSc in Nursing, Neonatal Intensive Care

Other areas of specialty/work

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Person responsible for updating data

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Web page address

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