Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Tactile-Kinesthetic Stimulation on weight gaining of preterm infants

Protocol summary

Summary

To determine the effects of 5 days of massage therapy on physiologic parameters and weight gaining of hospitalized stable preterm infants hospitalized in Fatemiye neonatal intensive care unit in Shahrood-Iran. Fifty one babies will be randomly allocated into test and control groups (27 and 24 neonate respectively). Tactile-Kinesthetic stimulation will be provided for three 20 minutes periods per day for 5 consecutive days to the test group, with the massages consisting of moderate pressure stroking in left and right lateral position and kinesthetic exercises consisting of flexion and extension of the limbs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805192324N1**
Registration date: **2006-06-20, 1385/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2006-06-20, 1385/03/30

Registrant information

Name
Maryam Keshavarz
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Shahrod University of medical Sciences

Expected recruitment start date

2006-06-20, 1385/03/30

Expected recruitment end date

2007-01-20, 1385/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tactile-Kinesthetic Stimulation on weight gaining of preterm infants

Public title

Effect of Tactile-Kinesthetic Stimulation on weight gaining of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 28 to 37 weeks, birth weight over 1500 gr, appropriate-for-gestational-age (AGA), apgar scores ≥7 at 1 and 5 min. No undergoing mechanical ventilation, congenital anomalies, central nervous system dysfunction (e.g., intraventricular hemorrhage or history of seizure), necrotizing enter colitis (NEC), sepsis, history of maternal drug abuse including: alcohol or illegal substances (as determined by the mother`s reported history or medical records). Infants will be excluded if they had such as hiccup, facial grimace, finger splay, clenched fingers, crying, heart rate over 200, intervention.

Age

To **1 year** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrood University of Medical Sciences
Street address
Hafte Tir Square
City
Shahrood
Postal code
Approval date
2005-07-16, 1384/04/25
Ethics committee reference number
8404

Health conditions studied

1

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

Primary outcomes

1

Description
weight gaining
Timepoint
daily
Method of measurement
with digital scale

Secondary outcomes

1

Description
Change in physiologic parameters including: Heart rate, Respiratory rate and Temperature
Timepoint
Immediately before intervention and during 20 min intervention
Method of measurement
Palse oximeter

Intervention groups

1

Description
No intervention in control group
Category
N/A

2

Description
Tactile-Kinesthetic Stimulation
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiye treatment & education center
Full name of responsible person
Maryam Keshavarz
Street address
22 Bahman Avenue
City
Shahrood

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Deputy of research affairs
Street address
Hafte Tir Square
City
Shahrood
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahrood 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
School of Nursing and Midwifery, Iran University of Medical Sciences
Full name of responsible person
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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