

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Iran University of Medical Sciences

Country

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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 enterocolitis (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

Hafta 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

Pulse 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

Hafta 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

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Tehran

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Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery - academic member

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

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Other areas of specialty/work**Street 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