Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of M technique on physiologic parameters, behavioral state, and weight gain in preterm neonates admitted to neonatal intensive care unit

Protocol summary

Summary

The purpose of this study was to determine the effect of applying M method on physiological, behavioral and weighing criteria in preterm infants admitted to the neonatal intensive care unit. This is a randomized clinical trial study. The population of this study included infants with fetal age of 28 to 37 weeks admitted to the intensive care unit of newborns in selected educational centers affiliated to Iran University of Medical Sciences. After the samples are selected, a written consent will be obtained from the parents of the infants, and the demographic data of these infants will be collected and recorded. Then, newborns are randomly assigned (blocked blocks) in the test and control group. All of the infants in the control group and the usual evolutionary care exam in the neonatal intensive care unit, such as skin contact, parental presence, neuropsychiatric assessments provided by a physician and clinical occupational therapist, use of conditional support and cyclic care Sleep and awakening. Neonates in the test group will receive M-massage as well as these treatments. In this study, 70 premature infants (28-30 weeks of age and birth weight 800 to 1400 g), normal abnormalities, cardiac abnormalities, chest tube, intracranial hemorrhage of more than grade 2, septic shock, Damaged skin, respiratory failure, tachycardia and persistent bradycardia.

General information

Acronym

M technique

IRCT registration information

IRCT registration number: **IRCT2017071135012N1**
Registration date: **2017-08-28, 1396/06/06**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-08-28, 1396/06/06

Registrant information

Name

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Name of organization / entity

iran university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

This research is approved by Iran University of Medical Sciences (Nursing and Midwifery Research Center) and its resources are provided from this place.

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of M technique on physiologic parameters, behavioral state, and weight gain in preterm neonates admitted to neonatal intensive care unit

Public title
Effect of massage on behavioral state and weigh gain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Age 28-30 weeks; Birth weight 800 to 1400 grams; Exclusion criteria: Existing abnormalities; Heart failure; Chest tube; need To oxygen more than 75%); stable tachycardia; stable bradycardia;
Age
From **1 day** old to **10 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **35**
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
Ethics committee of Iran University of Medical sciences
Street address
Shahid Hemmat Highway
City
Teharn
Postal code
Approval date
2017-03-14, 1395/12/24
Ethics committee reference number
IR.IUMS.REC 1395.29974

Health conditions studied

1

Description of health condition studied
Neonatal Prematurity
ICD-10 code
P07.3
ICD-10 code description
28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.

Primary outcomes

1

Description
physiological parameters
Timepoint
5 minutes before intervention as baseline data and then every minute for 7 minutes and then 10 minutes after intervention.
Method of measurement
the use of neonatal pals oximetry

2

Description
neonatal weight gain
Timepoint
Once before the intervention, then on a daily basis
Method of measurement
Baby scales

Secondary outcomes

1

Description
behavioral state
Timepoint
The duration of the intervention is based on the protocol of 7 minutes, each period of the intervention is from 8 am to 11 pm, based on the clinical situation and the readiness of the infant. Measure the behavioral status of 5 stings before the intervention and then every minute for 7 minutes and 10 minutes after the intervention is measured.
Method of measurement
Anderson Behavioral State Scale (ABSS)

Intervention groups

1

Description
The M technique is a structured massage method that aims at reducing stress in a neonatal, neonatal, neonatal, neonatal intensive care unit that can not tolerate traditional massage techniques. The protocols for this method, which have been extracted from the two previous studies, and the teaching or doing video produced by Mrs. Jane Buckle, are available to all members of the research team. The infants in the test group receive the following intervention: the infant is resting on the lower abdomen and the upper half of the helping agent is opened. The lower ends and the hips are well supported in the accumulated condition. One hand is taken in a cup. And with the other hand, the head and

the other extremities of the baby are protected. Pressures start at pressure 3 (0 to 10), which is rhythmic and stepwise. Each pressure is repeated 3 times. Pressures are lost with the second and third finger pads both. The duration of this technique is 5 minutes (approximately 20 seconds per pressure). This technique is achieved by touching and supporting and slowly finishing Finds.

Category

Behavior

2

Description

All newborns in the conventional evolutionary care group in the neonatal intensive care unit, such as skin contact, parental presence, neurodevelopmental assessments provided by the physician and clinical occupational therapist, use of conditional support and care for the sleep cycle, andake up will be received.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat rasol hospital

Full name of responsible person

mona alinejad naene

Street address

Sattar Khan Avenue, St. Niazi St. Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of Medical sciences

Full name of responsible person

Dr Mousavi

Street address

Hemmat exway- Iran University of Medical sciences

City

Tehran

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 of Iran 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 midwiefry, Iran University of Medical sciences

Full name of responsible person

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Master degree

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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