Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of applying neonate massage by the mother on the Feeding Tolerance and physiologic index of newborns admitted to the special neonatal ward

Protocol summary

Study aim

Assessment of the effect of applying neonate massage by the mother on Feeding Tolerance and physiologic index of newborns admitted to the special neonatal ward

Design

This study is a non-blinded clinical trial in the form of a parallel design with a control group. The research population will include all infants hospitalized in the intensive care unit of Imam Hossein Hospital in Isfahan. A total of 62 eligible infants will be selected conveniently. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted in Isfahan city hospital, is not blinded. The instructional manual of infant and newborn massage published by the Infant Health Department of the Ministry of Health, Treatment, and Medical Education is used for the intervention. Two one-hour training sessions will be held individually and face-to-face for mothers, and practical training on massage will be performed on a model.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The fetal age of the baby is 28-37 weeks; Birth weight is 1500 grams and more; The Apgar score of the first and fifth minutes is higher than 7; Hemodynamic stability Exclusion criteria: Severe asphyxia; High bilirubin level requires treatment with phototherapy; The presence of genetic or metabolic diseases

Intervention groups

In the intervention group, massage by trained mothers in three stages, including two sensory stages and one movement stage, three times a day and each time for 20 minutes after breastfeeding and changing the baby, in the morning, noon, and evening for 5 days on their baby will be done. In the control group, no intervention will be done.

Main outcome variables

Heart rate, oxygen saturation and breathing rate, Vomiting frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N199**
Registration date: **2023-04-13, 1402/01/24**
Registration timing: **prospective**

Last update: **2023-04-13, 1402/01/24**
Update count: **0**

Registration date

2023-04-13, 1402/01/24

Registrant information

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Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-05-31, 1402/03/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of applying neonate massage by the mother on the Feeding Tolerance and physiologic index of newborns admitted to the special neonatal ward

Public title
The effect of neonate massage on the Feeding Tolerance and physiologic index of newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The fetal age of the baby is 28-37 weeks Birth weight 1500 grams and more The Apgar score of the first and fifth minutes is higher than 7 Hemodynamic stability
Exclusion criteria:
severe asphyxia High bilirubin level requires treatment with phototherapy The presence of genetic or metabolic diseases
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random method. 62 cards are selected and numbers from 1-62 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group
Blinding (investigator's opinion)
Not 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 Khorasgan branch; Islamic Azad University
Street address
Vice Chancellor for Research Affairs, Daneshgah Blvd., Arghwanieh, J Sharghi Street
City
Isfahan
Province
Isfehan
Postal code
8155139998
Approval date
2023-03-13, 1401/12/22
Ethics committee reference number
IR.IAU.KHUISF.REC.1401.409

Health conditions studied

1

Description of health condition studied
Physiologic responses of premature infants
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
Heart rate
Timepoint
The beginning of the study and the end of the study
Method of measurement
Using monitoring

2

Description
Oxygen saturation
Timepoint
The beginning of the study and the end of the study
Method of measurement
Using monitoring

3

Description
Breathing rate
Timepoint
The beginning of the study and the end of the study
Method of measurement
Using monitoring

4

Description

Vomiting frequency

Timepoint

At the beginning of the study and 2 hours after gavage

Method of measurement

By a doctor

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, massage will performed by trained mothers in three stages, including two sensory stages and one movement stage, three times a day (morning, noon and evening), each time for 20 minutes after breastfeeding and changing the baby's diaper, for 5 days. In the movement stimulation phase, the baby is placed in a lying position on his back for 4 minutes and 6 flexion and extension movements (each movement of 10 seconds) will be performed in each of the organs, respectively, right arm, left arm, right leg, and left leg. In the tactile stimulation phase, the baby is again placed in a lying position on the right side for 8 minutes, 6 touch movements with medium pressure are performed for 10 seconds with the palm on each of the surfaces of the head, shoulder, left hand, and then in the position Lying on the baby's left side, six tactile movements are performed on each of the surfaces of the head, shoulder, right hand, back, and right leg.

Category

Treatment - Other

2

Description

In the control group, no intervention will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Faezeh Roustaei

Street address

Imam Hossein Hospital, Imam Khomeini street

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Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Faezeh Roustaei

Position

Nursing master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available