Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants admitted to neonatal intensive care units: A randomized controlled clinical trial

Protocol summary

Study aim
Comparison of the effects of abdominal and field massage on physiological indicators, weigh gain, the digestive function of premature newborns admitted to neonatal intensive care units

Design
A randomized clinical trial with a control group with three parallel arms will be conducted with 90 participants. The allocation sequence will be determined by a computer program with block sizes of 3 to 9 with an allocation ratio of 1:1:1. Allocation concealment will be centralized.

Settings and conduct
This clinical trial will be conducted on 90 premature neonates from the NICU of Shiraz University of Medical Sciences. The massage group will receive abdominal and field massage before feeding, twice a day, for 15 minutes, over 5 days, by the researcher. The control group will receive only routine care. In both abdominal and field massage groups, olive oil will be used for massage. In the I Love You massage group, the baby lies on his/her back with a head angle of 30 to 45 degrees. Abdominal massage will be applied in a clockwise direction above the intestinal area. In the field massage group, each massage will consist of 3 phases of 5 minutes and will be 15 minutes in total. All preterm neonates are fed with a nasogastric tube - French 6 or 8. The feeding protocol will be the same for all neonates.

Participants/Inclusion and exclusion criteria
Primary inclusion criteria: The neonate should be in the first 48 hours after birth; a 5th-minute Apgar score of 7 or higher; gestational age between 30 to 34 weeks; and weight between 1000 and 1750 grams. Primary exclusion criteria: cleft palate and lip, contraindication for massage, premature newborns with congenital anomalies, recent abdominal surgery.

Intervention groups
Field massage group; abdominal massage group; control group

Main outcome variables
Physiological indicators, weight gain, and digestive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221220056884N1**
Registration date: **2023-04-28, 1402/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-28, 1402/02/08**
Update count: **0**

Registration date
2023-04-28, 1402/02/08

Registrant information

Name
Sedigheh Khodabandeh Shahraki

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3132 5220

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-09-21, 1402/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants admitted to neonatal intensive care units: A randomized controlled clinical trial

Public title
A comparative study of abdominal and field massage on physiological indicators, weight gain, and digestive function of preterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The baby being in their first 48 hours after birth Feeding through a nasogastric tube - French 6 or 8 5th-minute Apgar being 7 or higher Gestational age between 30 to 34 weeks Absence of severe respiratory distress Weight between 1000 and 1750 grams No need for ventilation Absence of mother's addiction
Exclusion criteria:
Cleft palate and lip Any prohibition for massage All preterm infants with congenital abnormalities such as congenital heart disease, gastrointestinal tract abnormalities, hypoxic injury, respiratory failure, current or past history of necrotizing enterocolitis, suspected or confirmed sepsis Recent abdominal surgery
Age
From **2 days** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Premature babies in the NICU department who have the conditions to enter the study, using the random block method with the size of blocks of 3 and 9, including (abdominal massage group, field massage and control group) with a 1:1:1 allocation ratio in one of the groups Intervention and control will be placed. Allocation sequence will be determined using the computer program www.Random.org by a person not involved in the selection of the samples.
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluation of the outcome will be made by someone who is blinded to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Haft Bagh Alavi, Pardizeh, Kerman University of Medical Sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2023-02-27, 1401/12/08
Ethics committee reference number
IR.KMU.REC.1401.540

Health conditions studied

1

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

Primary outcomes

1

Description
Physiological indicators
Timepoint
Before the intervention, after the intervention
Method of measurement
Saadat Monitoring Machine

2

Description
weight gain
Timepoint
Before the intervention, after the intervention

Method of measurement
Seca scale made by Persia factory

3

Description
Digestive function
Timepoint
Before the intervention, after the intervention
Method of measurement
Syringe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The masseur in the intervention group gives her baby abdominal massage for 15 minutes at a certain time (9:00 a.m. and 9:00 p.m.) on five consecutive days (as trained).
Category
Treatment - Other

2

Description
Intervention group 2: The masseur gives her neonetals a field massage for 15 minutes at a certain time (9:00 am and 9:00 pm) on five consecutive days (as trained).Field massage is such that each massage will consist of 3 phases of 5 minutes and a total of 15 minutes, in the first and third phase, the baby will be placed on the stomach and the massage will be performed as follows: 1) from the top of the head to the neck and vice versa, 2) from the neck to the shoulders and vice versa, 3) from the upper back to the waist and vice versa, 4) from the shoulder to the hand and then in the reverse direction in both hands, 5) from the thigh to the ankle leg and then in the reverse direction on both legs. In each of the mentioned areas, 12 movements of 5 seconds will be performed. In the second phase, the baby will be in the vault position and the passive movements of flexion and extension of the arms and legs separately and both legs together will be performed in 5 stages of one minute, each stage will include 6 movements of 10 seconds. Takes
Category
Treatment - Other

3

Description
Control group: Newborns in the control group will receive the routine NICU care.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipur Hospital
Full name of responsible person
Golnoush Motamedi
Street address
Afzalipur Hospital, Imam Khomeini Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Davood Kalantar-Neyestanaki
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
personal
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
Kerman University of Medical Sciences
Full name of responsible person
Golnoush Motamedi
Position
Master's student in Neonatal Intensive Care Nursing
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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 still no plan to develop a program for sharing the data. According to the above sampling data time, the study will be completed by that time.
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