Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of abdominal massage and abdominal touch on gastrointestinal function, weight and comfort of premature infants hospitalised in the neonatal intensive care unit.

Protocol summary

Study aim

Comparison of the effects of abdominal massage and tactile stimulation on gastrointestinal function, weight, and comfort of infants admitted to the neonatal intensive care unit.

Design

the study is a clinical trial with a control group, a parallel design, non-blinded, with random allocation, conducted on 30 hospitalized newborns in the Neonatal Intensive Care Unit (NICU) (30 infants in the intervention group and 30 in the control group). Six-member block randomization is used.

Settings and conduct

Duration and groups: 5 days, group A receives abdominal massage and group B simple abdominal palpation for 15 minutes twice a day (9:00 AM and 9:00 PM); intervention one hour before feeding. With checking the baby's stability (vital signs, confirmed by the doctor), changing diapers if needed, washing hands; performed only if calm and alert. ; control group receives routine developmental care.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Preterm infants with stable physical and physiologic conditions, oral feeding, a birth weight over 1000 g, and a gestational age of 30–37 weeks, without any abnormalities. Exclusion criteria:The presence of any prohibitions on performing massage.

Intervention groups

Intervention: The researcher will, for 5 days, twice daily at 12-hour intervals (9:00 AM and 9:00 PM), one hour before infant feeding, for 15 minutes each time, perform abdominal massage for Group A and gentle abdominal touch for Group B. Both intervention groups and the control group will receive all routine department interventions according to developmental care.

Main outcome variables

AGastrointestinal function, weight, and comfort of premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N13**
Registration date: **2025-12-15, 1404/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-15, 1404/09/24**
Update count: **0**

Registration date

2025-12-15, 1404/09/24

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-22, 1404/06/31

Expected recruitment end date

2026-03-13, 1404/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of abdominal massage and abdominal touch on gastrointestinal function, weight and comfort of premature infants hospitalised in the neonatal intensive care unit.

Public title

Comparison of the effect of abdominal massage and abdominal touch on gastrointestinal function, weight and comfort of premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Apgar score at 5 minutes; birth weight over seven No defects or surgeries in the abdominal wall No connection to the ventilator Gestational age 32 to 37 weeks. Stability of the infant's clinical condition and absence of respiratory distress or congenital abnormalities

Exclusion criteria:

having intraventricular hemorrhage of grade 2 or more maternal addiction history according to documented evidence and self-report Weight less than 1000 grams

Age

From **30 days** old to **36 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Make Six blocks by drawing a card by the first mother. In each card, different states of the block are specified and the researcher will place babies in the specified group respectively. The above card is taken out of the pocket and the mother of the 6th baby again takes out a card from the envelope and the status of the next group of6 babies will be determined.

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 Iran University of Medical Sciences

Street address

Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty

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Province

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Postal code

1449614535

Approval date

2025-08-13, 1404/05/22

Ethics committee reference number

IR.IUMS.REC.1404.483

Health conditions studied

1

Description of health condition studied

Faster weight gain for premature babies

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Gastrointestinal function

Timepoint

The effect of abdominal massage and Simple touch on the infant's Gastrointestinal function, including weight, defication rate, and amount of breast milk fed, would be measured the day before the intervention and then daily (9 a.m. before startinf each intervention) for 5 consecutive days.

Method of measurement

function is measured by weighing the infant daily with a digital scale, recording 24-hour intake and output on the infant's sheet, and measuring abdominal circumference daily with a paper tape measure.

2

Description

Comfort

Timepoint

The effect of simple abdominal massage and simple touch on the infant's comfort level will be measured at the beginning of the study (before the intervention) and then for 5 consecutive days during breastfeeding after each type of intervention (twice a day, at 9 am and 9 pm).

Method of measurement

Infant comfort during feeding (COMFORT neo) will be measured.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group A: with low pressure and using an anti-allergy lotion, movements begin from the left side of the abdomen and proceed clockwise; includes an inverted L (right-to-left), a downward chest/abdomen movement, and an inverted U around the navel; movements are clockwise around the navel; knees toward the abdomen, thighs to the right; then the infant is placed prone and monitored.
Category
N/A

2

Description
Intervention group B: simple abdominal touch with the smallest pressure from below the ribs to the pelvis; responses are monitored; if positive, it continues; otherwise, the pressure is reduced or stopped; then the infant is returned to a resting position.
Category
N/A

3

Description
Control group: receiving standard neonatal intensive care that is based on developmental care, with data collection conducted according to the two intervention groups.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Hospital
Full name of responsible person
Dr.Mahnaz Shoghi
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2

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Sponsors / Funding sources

1

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The end of sampling till six months after article publishing.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used by researchers to conduct studies for the purpose of systematic reviews or meta-analyses, with the citation of the document. By sending a formal request to the project manager, the data file will be sent to them.

From where data/document is obtainable

Mahnaz Shoghi Email: shoghi.m@iums.ac.ir

What processes are involved for a request to access data/document

After sending a request to academic email, we will send our data files up to one week.

Comments