Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Effects of Abdominal Massage on Feeding Tolerance in Preterm Infants in Certain Hospitals of Isfahan

Protocol summary

Summary

Objective: this study attempts to determine effects abdominal massage could have on feeding tolerance in preterm infants hospitalized in the Neonatal Intensive Care Unit (NICU) in certain hospitals of Isfahan in 2015. Study design: randomized controlled trial. Study population: the population consisted of infants who were hospitalized in the NICU, were in the 28-32 week-old age range, weighed 1000-1800 grams, and had all inclusion criteria. Inclusion criteria: infants should be in the 28-32 week-old age range; infants should weigh1000-1800 grams; infants who have a medical prescription for a daily feeding of at least 20 cc/kg; infants who are breastfed; infants who suffer from feeding intolerance; infants should have no history of ileus (gastrointestinal atony), abdominal surgery, or any other problem forbidding them to receive abdominal massage; infants should be fed through the orogastric tube; parents should give consent to the examination of their infants; preterm infants should never suffer from major congenital anomalies such as congenital heart disease, digestive-system disorders, hypoxic injury, respiratory failure with mechanical ventilation, history of necrotizing enterocolitis (NEC), or (suspected) sepsis; preterm infants should show no symptoms of intracranial hemorrhage; preterm infants should never need a ventilator. Exclusion criteria: parents' withdrawal for infants' participation in the study; infants' discharge or death before the end of the intervention period; infants' becoming unwell in the course of illness and during the study, which would interfere with the intervention for any reason. Sample size: 64 (32 in the intervention group and 32 in the control group). Study intervention(s): abdominal massage. Primary outcome variables: gastric residual volume, abdominal circumference, vomiting frequency, and defecation frequency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072723216N3**
Registration date: **2016-08-26, 1395/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name
Said Amini Rarani
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Science

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of Abdominal Massage on Feeding Tolerance in Preterm Infants in Certain Hospitals of Isfahan

Public title
Effects of Abdominal Massage on Feeding Tolerance in Preterm Infants

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: infants should be in the 28-32 week-old age range; infants should weigh1000-1800 grams; infants who have a medical prescription for a daily feeding of at least 20 cc/kg; infants who are breastfed; infants who suffer from feeding intolerance; infants should have no history of ileus (gastrointestinal atony), abdominal surgery, or any other problem forbidding them to receive abdominal massage; infants should be fed through the orogastric tube; parents should give consent to the examination of their infants; preterm infants should never suffer from major congenital anomalies such as congenital heart disease, digestive-system disorders, hypoxic injury, respiratory failure with mechanical ventilation, history of necrotizing enterocolitis (NEC), or (suspected) sepsis; preterm infants should show no symptoms of intracranial hemorrhage; preterm infants should never need a ventilator. Exclusion criteria: parents' withdrawal for infants' participation in the study; infants' discharge or death before the end of the intervention period; infants' becoming unwell in the course of illness and during the study, which would interfere with the intervention for any reason.

Age
To **29 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Isfahan University Of Medical Sciences

Street address
Hezarjerib Street, Isfahan, Iran

City
Isfahan,

Postal code
8174673461

Approval date
2016-05-21, 1395/03/01

Ethics committee reference number
Ir.mui.rec.1395.3.001

Health conditions studied

1

Description of health condition studied
Feeding Tolerance inInfants

ICD-10 code
P92.8

ICD-10 code description
Other feeding problems of newborn

Primary outcomes

1

Description
Gastric residual volume

Timepoint
Before and after intervention

Method of measurement
with syring

2

Description
Abdomen circumferenc

Timepoint
Before and after intervention

Method of measurement
With meter

3

Description
Vomiting

Timepoint
Every working shift

Method of measurement
Frequency

4

Description
Defecation

Timepoint
Every working shift

Method of measurement
Frequency

Secondary outcomes

empty

Intervention groups

1

Description
Giving infants abdominal massage one hour after feeding them for 10 minutes twice a day and repeating it for 5 days.
Category
Other

2

Description
No intervention was performed in the control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Street address
City
Isahan

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Isfahan University of Medcal Sciences
Full name of responsible person
Dr Mehdi Nematbakhsh
Street address
Isfahan University of Medcal Sciences, Hezarjerib Street, Isfahan, Iran
City
Isfahan

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, Isfahan University of Medcal 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
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty