

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 weigh 1000-1800 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3522 6158

Email address

ghadami@mui.ac.ir

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 weigh 1000-1800 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

lr.mui.rec.1395.3.001

Health conditions studied

1

Description of health condition studied

Feeding Tolerance in Infants

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 syringe

2

Description

Abdomen circumference

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 Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

Street address

Isfahan University of Medical 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 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**

Isfahan University of Medical Sciences

Full name of responsible person

Mahin Shaeri

Position

Master Science of Nursing

Other areas of specialty/work**Street address**

No. 44, Tus Blvd., Mashhad, Iran

City

Mashhad

Postal code**Phone**

+98 51 3257 6309

Fax**Email**

mahinshaeri2013@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

PhD

Other areas of specialty/work**Street address**

No.127, 22 Bahman alley, Raran st., Khorasgan city, Isfahan, Iran

City

Khorasgan

Postal code**Phone**

+98 31137927561

Fax

Email

ghadami@nm.mui.ac.ir

Web page address

+98 31 3522 6158

Fax**Email**

Aminix11@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Amini Rarani Said

Position

Master Science of Nursing

Other areas of specialty/work**Street address**

No.127, 22 Bahman alley, Raran st., Khorasgan city,
Isfahan, Iran

City

Khorasgan

Postal code

8159314853

Phone**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