

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of abdominal massage on the residual gastric volume and physiological responses in hospitalized preterm infants in neonatal intensive care unit

Protocol summary

Study aim

Investigating the effect of abdominal massage on the residual gastric volume and physiological responses in preterm infants

Design

Clinical trial with parallel control group, without blinding

Settings and conduct

The researcher will refer to Ali ebn Abitaleb hospital of Rafsanjan and then the sample according to inclusion criteria will be divided to two groups. Intervention will perform twice a day . Gastric residual volume and physiological responses of newborns before and after intervention are measured and recorded.

Participants/Inclusion and exclusion criteria

30 to 34 weeks of gestational age; lack of congenital anomalies and abdominal defects; no need to mechanical ventilation

Intervention groups

Intervention group: abdominal massage will be used for 15 minutes, twice a day and for a 5 days period. Gastric residual volume and physiological responses of newborns before and after intervention are measured and recorded. Control group: just will receive routine care. Gastric residual volume and physiological responses of newborns before and after intervention are measured and recorded.

Main outcome variables

Physiological responses; gastric residual volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180913041030N1**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **prospective**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Roghayeh Mehdipour Rabori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5220

Email address

r_mehdipour@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of abdominal massage on the residual gastric volume and physiological responses in hospitalized preterm infants in neonatal intensive care unit

Public title

Investigating the effect of abdominal massage on the residual gastric volume and physiological responses in

preterm infants

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 30 to 34 weeks of gestational age Feeding through nasogastric tube No need to mechanical ventilation
Exclusion criteria:
 Abdominal defects and congenital anomalies Prohibition of massage in order to physician opinion Feeding intolerance

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample will be selected from preterm infants according to inclusion criteria, then by using of sortition, infants will be placed in two equal groups

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 Kerman University of Medical Sciences
Street address
 Campus of Kerman medical science university, Haft-Bagh Highway
City
 Kerman
Province
 Kerman
Postal code
 7616913555
Approval date
 2019-01-29, 1397/11/09
Ethics committee reference number
 IR.KMU.REC.1397.413

Health conditions studied

1

Description of health condition studied

Physiological responses

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Gastric residual volume

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Arterial oxygen saturation

Timepoint

Before and after intervention

Method of measurement

Pulseoximetry

2

Description

Heart rate

Timepoint

Before and after intervention

Method of measurement

Pulseoximetry

3

Description

Gastric residual volume

Timepoint

Before and after intervention

Method of measurement

Measurement of residual volume with syringe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: abdominal massage will be used for 15 minutes, twice a day and for a 5 days period. Gastric residual volume and physiological responses of newborns before and after intervention are measured and recorded.

Category

Other

2

Description

Control group: just will receive routine care. Gastric residual volume and physiological responses of newborns before and after intervention are measured and recorded.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn abitaleb hospital

Full name of responsible person

Azadeh Moghadam

Street address

Hazrat Ali ebn Abitaleb hospital, Mofateh Blvd.,

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Rafsanjan

Province

Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Dehnaviyeh

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Kerman medical sciences university, Haft Bagh highway, Kerman

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Email

rdehnavi@gmail.com

Web page address

http://kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Roghayeh Mehdipour Rabori

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Medical University,

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

Relied on secrecy

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