

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of body position on the gastric residual volume in preterm neonates admitted to the NICU of Imam Reza Hospital (AS) in 2016

Protocol summary

Summary

The aim of this study is to investigate the effect of body position on the gastric residual volume in preterm neonates. Inclusion criteria includes feeding through nasogastric or orogastric tube, feeding by breast milk, not attached to the ventilator. Exclusion criteria includes increase in respiratory distress after breast feeding. Study population: premature neonates hospitalized in neonatal intensive care unit. Sample size: 135 Intervention: Using the lottery Patients are placed in three groups. Patients in each group are placed in supine, prone, and right side positions for an hour. The sort orders of positions are as below: first group: supine, right side and prone; second group: right side, supine and prone; and third group: prone, supine and right side. In every position, at first, gastric residual volume is measured and then breastfeeding will be start through gavage. After one hour, the gastric residual volume is measured again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404134736N6**

Registration date: **2016-01-31, 1394/11/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-31, 1394/11/11

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of body position on the gastric residual volume in preterm neonates admitted to the NICU of Imam Reza Hospital (AS) in 2016

Public title

The effect of body position on the gastric residual volume in preterm neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 30 and 36 weeks; feeding through nasogastric- or orogastric tube; feeding by breast milk; not attached to the ventilator; stable vital signs; Lack of congenital defects. Exclusion criteria: neonate death during the study; an increase in respiratory distress after breast feeding; unstable vital signs.

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: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Comitee of Kermanshah University of Medical Sciences

Street address

kermanshah University of Medical Sciences, Shahid Beheshty Blvd., Kermanshah

City

Kermanshah

Postal code

Approval date

2015-12-28, 1394/10/07

Ethics committee reference number

kums.rec.1394.279

Health conditions studied

1

Description of health condition studied

preterm neonate

ICD-10 code

P78.9

ICD-10 code description

Perinatal digestive system disorder, unspecified

Primary outcomes

1

Description

gastric residual volume

Timepoint

one hour after milk gavage

Method of measurement

Measurement of gastric residual through the lavage of gastic content

Secondary outcomes

empty

Intervention groups

1

Description

The Patients in first group are placed in supine, right side and prone for an hour. In every position, at first, gastric residual volume is measured and then breastfeeding will be start through gavage. After one hour, the gastric residual volume is measured again.

Category

Prevention

2

Description

The Patients in second group are placed in right side, supine and prone for an hour. In every position, at first, gastric residual volume is measured and then breastfeeding will be start through gavage. After one hour, the gastric residual volume is measured again.

Category

Prevention

3

Description

The Patients in third group are placed in prone, supine and right side for an hour. In every position, at first, gastric residual volume is measured and then breastfeeding will be start through gavage. After one hour, the gastric residual volume is measured again.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Alireza Khatony

Street address

kermanshah University of Medical Sciences, Shahid Beheshty Blvd., Kermanshah

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Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Behrooz Hamzeh

Street address

kermanshah University of Medical Sciences, Shahid Beheshty Blvd., Kermanshah

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Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Khatony

Position

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Other areas of specialty/work

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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