Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of prone and right lateral positions on gastric residual volume in preterm infants

Protocol summary

Study aim

The main objective: Evaluation the effect of prone and right lateral positions on gastric residual volume in preterm infants

Design

This study was a cross-sectional clinical trial. 52 infants with inclusion criteria were selected by objective method and entered the study. Then in the form of random block assignment (quadruple block), they will fall into two groups A and B. Babies of group A are placed in position on the abdomen and group B in the position on the right side (the babies will be placed in the position during placement or the same nest).

Settings and conduct

This study will be carried out in NICU and neonates in Amirkabir Hospital in Arak, and the 17th Shahrivar Hospital in Saveh. The study was done so that premature infants according to entry criteria enter the study, then before and after feeding through gavage at minutes 30, 60, 90, and 120, the gastric residual volume in both prone and right lateral positions will be measured by gavage syringe which will also be in milliliters, and will be written in the checklist for each baby (the infant will stay for 120 minutes in each position). Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The consent of the infant's parents to intervene Breast feeding by gavage The infants from 28 to 36 weeks The weight between 800 and 2500 grams The hospitalization for at least 2 days The lack of connection to the ventilator Exclusion criteria: Resumption of oral nutrition Parents' unwillingness to continue the study The presence of digestive problems Intravntricular hemorrhage Necrotizing enterocolitis Apnea Seizure Infant death

Intervention groups

In this study, premature infants that have been born between the 28 and 36 weeks uterine age will be interfered. infants who come to the study according to the criteria of entry, according to the codes obtained by statistical analysis of the blocking, receive the first feeding in one position and the next time in the other position, and the gastric residual volume will be measured before the gavage and It will also be measured in both minutes at 30, 60, 90 and 120 after the gavage. This study is due to the fact that it is cross-linked, and each group is also a control group.

Main outcome variables

Improve the infant's development, reducing the complications associated with premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037733N1**
Registration date: **2017-12-19, 1396/09/28**
Registration timing: **prospective**

Last update: **2017-12-19, 1396/09/28**
Update count: **0**

Registration date

2017-12-19, 1396/09/28

Registrant information

Name

Mehran Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3417 3505

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01
Expected recruitment end date
2018-07-23, 1397/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of prone and right lateral positions on gastric residual volume in preterm infants

Public title
The effect of two positions on the gastric residual volume of premature infants
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The consent of the infant's parents to intervene Breast feeding by gavage The infants with uterine age from 28 to 36 weeks The weight between 800 and 2500 grams The hospitalization for at least 2 days The lack of connection to the ventilator
Exclusion criteria:
Resumption of oral nutrition Parents' unwillingness to continue the study The presence of digestive problems Intravntricular hemorrhage Necrotizing enterocolitis Apnea Seizure Infant death
Age
From **7 months** old to **9 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Infants eligible for inclusion are selected in a goal-based manner and are enrolled in the study. Then in the form of a randomized block assignment (quadruple block), which will be provided by the relevant software and by the statistics expert, they will fall into two groups A and B. Babies of group A are placed in position on the abdomen and group B in the position on the right side (the newborns will be placed inside the nest during placement). after a certain amount of gastric residual volume measurement, the position of both groups will be change.
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
Ethics committee of Arak University of Medical Sciences
Street address
Third Floor, blue Wing, Payambar aazam (SAW) University Complex, Basij SQ, Sardasht region
City
Arak
Province
Markazi
Postal code
6941-7-38481
Approval date
1994-04-03, 1373/01/14
Ethics committee reference number
IR.ARAKMU.REC.1396.192

Health conditions studied

1

Description of health condition studied
Prematurity
ICD-10 code
Z76.2
ICD-10 code description
Encounter for health supervision and care of other healthy infant and child

Primary outcomes

1

Description
Gastric Residual Volume
Timepoint
Before the gavage, as well as at 30, 60, 90 and 120 minutes after gavage
Method of measurement
Gavage syringe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infants that in the group (A), will be placed in the prone position and the gastric residual volume will be measured before the gavage, and at 90, 60, 30 and 120 minutes after the gavage, and after 3 hours from the start of the gavage, this group (A) of infants will be placed in the right lateral position position and gastric residual volume will be measured before the gavage, and also at 90, 60, 30 and 120 minutes after the gavage.

Category
N/A

2

Description
Intervention group: Infants that in the group (B), will be placed in the right lateral position and the gastric residual volume will be measured before the gavage, and at 90, 60, 30 and 120 minutes after the gavage, and after 3 hours from the start of the gavage, this group (B) of infants will be placed in the prone position position and gastric residual volume will be measured before the gavage, and also at 90, 60, 30 and 120 minutes after the gavage.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonatal Intensive Care Unit and Neonatal waed in Amirkabir hospital

Full name of responsible person
Mehran Akbari

Street address
Nursing Square, Alam al-Hoda Street, Shahid Shiroudi Street

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2

Recruitment center

Name of recruitment center
Neonatal Intensive Care Unit in17 Shahrivar hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjmandzadegan

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Deputy of research and technology, Payambar aazam (SAW) University Complex, Basij SQ, Sardasht region

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mehran Akbari

Position
MSc Student in pediatric nursing

Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available