

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 Intraventricular 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)

##### Phone

+98 86 3417 3505

##### Email address

m.akbari@arakmu.ac.ir

##### 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 Intraventricular 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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#### Province

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#### Postal code

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#### Phone

+98 86 3313 4717

#### Email

m.akbari@arakmu.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Neonatal Intensive Care Unit in17 Shahrivar hospital

#### Full name of responsible person

Mehran Akbari

#### Street address

Shahrivar Hospital, Motahari St., Modarres Blvd,

Saveh town

#### City

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#### Province

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#### Phone

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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

#### Street address

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

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Arak

#### Province

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#### Postal code

3848176941

#### Phone

+98 86 3417 3645

#### Email

arjomandzadegan@arakmu.ac.ir

### 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****Contact****Name of organization / entity**

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

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**Full name of responsible person**

Mehran Akbari

**Position**

MSc student in pediatric nursing

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**Email**

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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