

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of nest position versus supine position on gastric residual volume after gavage in premature neonates: a single-blind crossover randomized clinical trial

Protocol summary

Study aim

To assess the effect of nest position versus supine position on gastric residual volume after gavage in premature neonates

Design

This a single-blind crossover randomized clinical trial, phase II, in which 70 eligible premature neonates will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible premature neonates who will refer to Amiralmomenin Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 32 to 37 weeks Birth weight less than 3000 g Prematurity Exclusion criteria: Gastrointestinal abnormalities Need to incubator Genetic disease

Intervention groups

Intervention group: Putting neonate in the nest position during gavage two times with 2 hours interval Control group: Putting neonate in the supine position during gavage two times with 2 hours interval

Main outcome variables

Primary outcome: Measuring the gastric residual volume after gavage immediately after intervention through physical examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N206**

Registration date: **2018-02-15, 1396/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-15, 1396/11/26**

Update count: **0**

Registration date

2018-02-15, 1396/11/26

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of nest position versus supine position on gastric residual volume after gavage in premature neonates: a single-blind crossover randomized clinical trial

Public title

Effect of nest position versus supine position on gastric

residual volume after gavage in premature neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 32 to 37 weeks Birth weight less than 3000 g

Prematurity

Exclusion criteria:

Gastrointestinal abnormalities Need to incubator Genetic disease

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots. For this purpose, we write intervention and control on two paper sheets. Then every neonate will be assigned either to intervention or to control group one basis of drawing lots.

Blinding (investigator's opinion)

Single blinded

Blinding description

Neonates will be unaware of the type of intervention. Therefore, the trial will be run as single-blind

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Province

Hamadan

Postal code

6517838695

Approval date

2017-11-13, 1396/08/22

Ethics committee reference number

IR.UMSHA.REC.1396.545

Health conditions studied

1

Description of health condition studied

Premature neonates

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

Measuring the gastric residual volume after gavage

Timepoint

Immediately after intervention

Method of measurement

Through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Putting neonate in the nest position during gavage two times with 2 hours interval

Category

Other

2

Description

Control group: Putting neonate in the supine position during gavage two times with 2 hours interval

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Fatemeh Sargolzaei

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Sponsors / Funding sources

1

Sponsor

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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

Hamedan 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
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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