

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigating the effect of body posture change on digestive tolerance in very low birth weight premature babies fed with enriched breast milk

Protocol summary

Study aim

Investigating the effect of changing body position on digestive tolerance in very low birth weight premature babies fed with enriched breast milk

Design

Clinical trial with two intervention groups, randomized, on 62 very low birth weight premature babies

Settings and conduct

The location of the neonatal special care department of Shahid Sadougi and Shahada Kargar Hospital in Yazd, the demographic information questionnaire of the newborn is completed. Babies are randomly assigned to two groups. In this study, enriched breast milk is given to the baby twice (8:00 am and 2:00 pm) and then in the first time, he is fed in the position of lying on his stomach and in the second time of feeding he is placed in the position of lying on his right side. Gastrointestinal tolerance is checked according to the checklist three hours after feeding, and a rest period (only breast milk is given) is considered between feeding with enriched breast milk. Also, other items related to digestive tolerance including abdominal distention, the presence of vomiting is checked and recorded according to the checklist.

Participants/Inclusion and exclusion criteria

Entry criteria: 1- Premature baby weighing 1000-1500 grams 2- Fetal age 26-31 weeks 3- Oral feeding with nasogastric tube 4- Breastfeeding 5- Stability of clinical condition 6- Not being prohibited by the attending physician to lie down on the stomach and right side Non-entry criteria: 1-Having congenital anomalies 2-Severe asphyxia 3-Having symptoms of digestive problems

Intervention groups

Very low birth weight preterm infants fed with fortified breast milk

Main outcome variables

Digestive tolerance of fortified breast milk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230328057781N1**

Registration date: **2023-05-02, 1402/02/12**

Registration timing: **prospective**

Last update: **2023-05-02, 1402/02/12**

Update count: **0**

Registration date

2023-05-02, 1402/02/12

Registrant information

Name

Marzieh Poorakrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3282 9120

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-15, 1402/02/25

Expected recruitment end date

2023-10-17, 1402/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of body posture change on digestive tolerance in very low birth weight premature babies fed with enriched breast milk

Public title

The effect of changing body position on digestive tolerance of fortified breast milk in premature infants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature baby weighing 1000-1500 grams Fetal age 26-31 weeks Oral feeding with a nasogastric tube Breast feeding Stability of clinical condition Not being forbidden by the attending physician to lie down on the stomach and right side

Exclusion criteria:

Having congenital abnormalities severe asphyxia Having symptoms of digestive problems

Age

From **182 days** old to **217 days** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization tool The file number of premature babies is written and placed in an envelope, and then by taking out the file number of each baby, they are placed in a group.

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**

کمیته اخلاق دانشگاه علوم پزشکی یزد

Street address

صفاییه بلوار پرفسور حسایی

City

یزد

Province

Yazd

Postal code

891583135

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR. SSU.REC.1402.001

Health conditions studied**1****Description of health condition studied**

Gastrointestinal intolerance

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Gastrointestinal intolerance

Timepoint

Measurement of digestive intolerance at the beginning of the study and 3 hours after feeding in lying positions on stomach and right side.

Method of measurement

Gastrointestinal intolerance checklist

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group: Very low birth weight premature babies fed with enriched breast milk are placed on their stomachs in the first feeding and after three hours the checklist related to digestive tolerance is completed for these babies and in the second feeding of these babies After feeding, he is placed on his right side and the checklist is completed three hours later. The second intervention group: very low birth weight premature babies fed with enriched breast milk are placed in the right side lying position in the first feeding, and three hours later the checklist is completed and in the next feeding, they are placed in the stomach lying position.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Ssadoughi Hospital and Shohadai Kargar

Hospita

Full name of responsible person

Marzieh Purakremi

Street address

Shahid Qandi Blvd, Ibn Sina Ave

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sadoghi-hospital@ssu.ac.ir

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Full name of responsible person

Marzieh Poorakremi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargoui

Street address

Shahid Dr. Bahnar Square

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Yazd

Province

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Grant name

Grant code / Reference number

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

No

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Hossein Lookzadeh

Position

Non-faculty specialist doctor

Latest degree

Subspecialist

Other areas of specialty/work

infants

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Marzieh Poorakremi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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