Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
m.poorakrami@stu.ssu.ac.ir

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 حسابی
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

City
yazd

Province
Yazd

Postal code
۸۹۱۵۸۸۷۸۵۷

Phone
+98 35 3822 4000

Email
sadoghi-hospital@ssu.ac.ir

Web page address

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

City
Yazd

Province
Yazd

Postal code
8916978477

Phone
+98 35 3724 0171

Email
samat@ssu.ac.ir

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

Full name of responsible person
Marzieh Poorakremi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Emam Ave , Dadgodtari st. 4th Alley

City
Abarkooh

Province
Yazd

Postal code
8931913497

Phone
+98 35 3282 9120

Email
mpoorakrami64@gmail.com

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

Street address
Pakenjad Blvd., 12th St., Pone Alley, No 3

City
Yazd

Province
Yazd

Postal code
8916976535

Phone
+98 35 3728 1723

Email
drlookzadeh@gmail.com

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

Street address

Dadgostari Ave, 4th Alley

City
Abarkooh

Province
Yazd

Postal code
8931913497

Phone
+98 35 3282 9120

Email
mpoorakrami64@gmail.com

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