Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of hydrolyzed formula and standard formula in the first two weeks of life in preterm infants less than 34 weeks on improving nutritional tolerance and the prevalence of necrotizing enterocolitis.

Protocol summary

Study aim

The effect of hydrolyzed formula and standard formula in premature infants on improving nutritional tolerance and prevalence of necrotizing enterocolitis.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 104 patients. Excel software rand function was used for randomization.

Settings and conduct

Clinical trial on 104 premature infants during 1398 and 1399 in the NICU of Akbarabadi Hospital and Hazrat Ali Asghar Hospital. Each patient was randomly assigned to two treatments 1 and 2 (52 people in each group), respectively. . After two weeks, the improvement of nutritional tolerance and the prevalence of necrotizing enterocolitis in both groups were evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants/ less than 34 weeks deprived of breast milk / without congenital underlying disorders Exclusion criteria: Infants with dissatisfaction of parents or addicted parents, asphyxia Apgar fifth minute less than seven, IUG-R, and congenital anomalies.

Intervention groups

The intervention group is infants less than 34 weeks of age who do not have access to breast milk for any reason. They are fed with hydrolyzed formula. The control group includes infants less than 34 weeks of age who are not available breast milk for any reason. They are fed according to the standard formula.

Main outcome variables

Nutritional tolerance in infants, risk of necrotizing enterocolitis, length of hospital stay, prevalence of sepsis in preterm infants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160120026115N7**
Registration date: **2022-01-17, 1400/10/27**
Registration timing: **retrospective**

Last update: **2022-01-17, 1400/10/27**
Update count: **0**

Registration date

2022-01-17, 1400/10/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of the effect of hydrolyzed formula and standard formula in the first two weeks of life in preterm infants less than 34 weeks on improving nutritional tolerance and the prevalence of necrotizing enterocolitis.

Public title
Effect of hydrolyzed formula and standard formula in the first two weeks of life in preterm infants
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Infants less than 34 weeks gestationally deprived of breast milk Infants without underlying congenital disorders
Exclusion criteria:
Infants were excluded from the study with parental dissatisfaction. Infants from addicted parents were excluded from the study. Infants with asphyxia were excluded from the study. Infants with a fifth minute Apgar score of less than seven were excluded from the study. Infants with IUG-R were excluded from the study. Infants with congenital anomalies were excluded from the study.
Age
From **1 day** old to **14 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study is done by simple randomization method using Rand function of Excel software. First, 104 random numbers are created in a column using the Rand function. Then in the second column, from the numbers one to 104, new columns are inserted in front of each random code. Finally, in the third column, 52 lines are filled with code A and 52 lines with code B are filled. After arranging the size of the first column numbers using the software, by maintaining their connection to the second and third column numbers, a random sequence in the third column is ready. The numbers in the second column, each assigned to one of two groups based on the corresponding row in the third column, can be used as the row code used in hiding.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The powdered milk of both groups are packed in containers of the same shape and after preparing a random list by a person outside the executing group and receiving the interventions, they are labeled based on the codes obtained in randomization. The sequence of random codes will be hidden from this person (or the principal investigator's representative for blindness) until the end of the study, and will only be opened at the request of the principal investigator if necessary to avoid endangering the lives of the volunteers.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat highway
City
Tehran
Province
Tehran
Postal code
1494868871
Approval date
2020-07-22, 1399/05/01
Ethics committee reference number
IR.IUMS.FMD.REC.1399.478

Health conditions studied

1

Description of health condition studied
Necrotizing enterocolitis
ICD-10 code
P77.9
ICD-10 code description
Necrotizing enterocolitis in newborn, unspecified

Primary outcomes

1

Description
Improvement in nutritional tolerance
Timepoint
From the start of feeding the baby to the time of discharge from the hospital
Method of measurement

Clinical examination corresponding to the disease

2

Description
Reducing the incidence of necrotizing enterocolitis in premature infants
Timepoint
From the start of feeding the baby to the time of discharge from the hospital
Method of measurement
Clinical and laboratory examination corresponding to the disease

Secondary outcomes

1

Description
Duration of hospital stay
Timepoint
From the start of feeding the baby to the time of discharge from the hospital
Method of measurement
Number of days of hospitalization based on the contents of the file

2

Description
sepsis
Timepoint
From the start of feeding the baby to the time of discharge from the hospital
Method of measurement
Positive blood culture

Intervention groups

1

Description
In the intervention group, the hydrolyzed formula is used for feeding in all meals. The hydrolyzed formula in all members of the intervention group was from the same brand (Aptamil / Nutricia).How to prepare milk powder according to the manufacturer's instructions was one measure per 30 cc of water.
Category
Prevention

2

Description
Control group: The regular formula is used for feeding in all meals. The regular formula in all members of the intervention group was from the same brand (Aptamil / Nutricia). How to prepare milk powder according to the manufacturer's instructions was one measure per 30 cc of water.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi hospital
Full name of responsible person
Mandana Kashaki
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Sponsors / Funding sources

1

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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
Iran 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

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Iran University of Medical Sciences
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Mandana Kashaki
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Associated professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
The access period starts one year after the results are published.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
The data are allowed for further studies on this research topic.
From where data/document is obtainable
Leila Irani/ Iran University of Medical Sciences/ Iran University of Medical Sciences, Hemmat highway/ or Email address: kashakimd@gmail.com
What processes are involved for a request to access data/document
Written request or email
Comments