

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Name

Mandana Kashaki

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5563 2277

##### Email address

kashakimd@gmail.com

#### 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

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Tehran

**Province**

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**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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Akbar Abadi Hospital, Molavi Ave

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## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Leila Irani

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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

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mandana Kashaki

**Position**

Associated professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

