

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Investigation and comparison of the effect of early and late breast milk enrichment on preterm infants

#### Protocol summary

##### Study aim

determination and comparison of the effect of early and late breast milk enrichment on preterm infants

##### Design

Clinical trial with parallel groups

##### Settings and conduct

90 Preterm infants admitted to NICU at Hajar Hospital in Shahrekord randomly divided into 3 groups of 30. Then breast milk enrichment for infants is started based on the intervention group at a certain time and continues to 4 weeks. Height, weight and head circumference of infants are measured at the birth time and 4 weeks after birth.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants with Gestational age of 28 to 32 weeks with birth body weight less than 2000 g  
Exclusion criteria: The presence of Any congenital anomalies; formula feeding

##### Intervention groups

90 Preterm infants entered the study. On the first day of lactation Infants weighing less than 1000 grams receive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams receive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams receive More volume based on their tolerance every 2-3 hours through gavage. After the first day, lactation increases by 10-20 cc/ kg /day and up to 200-100 cc /kg / day. In the first group, when the amount of milk received reached 30 cc kg / day, the second group when reached 70 cc kg / day and the third group when reached 100 cc / kg /day, the interventions begin. In this way 4.4 g of the supplement of aptamil FMS ( NUTRICIA) is dissolved in each 100 cc of breast milk and it is given to the infant based on the amount of milk received by the infant per day through gavage. It contains 1 g of protein, 0g of fat, 2.7g of carbohydrate and a certain amount of some salts and vitamins. Breast milk enrichment continues for up to 4 weeks after birth.

##### Main outcome variables

height; weight; head circumference

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171030037093N3**

Registration date: **2019-02-23, 1397/12/04**

Registration timing: **retrospective**

Last update: **2019-02-23, 1397/12/04**

Update count: **0**

##### Registration date

2019-02-23, 1397/12/04

##### Registrant information

##### Name

Sadra Ansari pour

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3650 3487

##### Email address

st\_ansari.s@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-07, 1397/07/15

##### Expected recruitment end date

2019-03-06, 1397/12/15

##### Actual recruitment start date

2017-11-11, 1396/08/20

##### Actual recruitment end date

2018-11-01, 1397/08/10

**Trial completion date**

2018-11-01, 1397/08/10

**Scientific title**

Investigation and comparison of the effect of early and late breast milk enrichment on preterm infants

**Public title**

Effect of breast milk enrichment on early infants

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Premature infants (28-32 weeks) weighing less than 2000 grams enter the study With the consent of the infant's parents

**Exclusion criteria:**

any Congenital anomalies Formula feeding

**Age**

From **1 day** old to **28 days** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

Actual sample size reached: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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**

Ethics Committee of Shahrekord University of Medical Sciences

**Street address**

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713492

**Approval date**

2018-09-23, 1397/07/01

**Ethics committee reference number**

IR.SKUMS.REC.1397.145

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

breast Milk enrichment in preterm infants

**ICD-10 code**

P07.3

**ICD-10 code description**

Preterm [premature] newborn [other]

**Primary outcomes****1****Description**

infant's weight

**Timepoint**

At the beginning of birth and 4 weeks after birth

**Method of measurement**

Scale

**2****Description**

infant's head circumference

**Timepoint**

At the beginning of birth and 4 weeks after birth

**Method of measurement**

Meter

**3****Description**

infant's height

**Timepoint**

At the beginning of birth and 4 weeks after birth

**Method of measurement**

Meter

**Secondary outcomes**

empty

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

First intervention group: On the first day of lactation Infants weighing less than 1000 grams receive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams receive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams receive More volume based on their tolerance every 2-3 hours through gavage. After the first day, lactation increases by 10-20 cc / kg / day and up to 200-100 cc / kg / day. In this group, when the amount

of milk received reached 30 cc kg / day, the interventions begin. in this way 4.4 g of the supplement of aptamil FMS ( NUTRICIA) is dissolved in each 100 cc of breast milk and it is given to the infant based on the amount of milk received by the infant per day through gavage .it contains 1 g of protein, 0g of fat, 2.7g of carbohydrate and a certain amount of some salts and vitamins.Breast milk enrichment continues for up to 4 weeks after birth

#### Category

Prevention

### 2

#### Description

Second intervention group: On the first day of lactation Infants weighing less than 1000 grams receive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams receive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams receive More volume based on their tolerance every 2-3 hours through gavage. After the first day,lactation increases by 10-20 cc/ kg /day and up to 200-100 cc /kg / day.In this group, when the amount of milk received reached 70 cc kg / day, the interventions begin. in this way 4.4 g of the supplement of aptamil FMS ( NUTRICIA) is dissolved in each 100 cc of breast milk and it is given to the infant based on the amount of milk received by the infant per day through gavage .it contains 1 g of protein, 0g of fat, 2.7g of carbohydrate and a certain amount of some salts and vitamins.Breast milk enrichment continues for up to 4 weeks after birth.

#### Category

Prevention

### 3

#### Description

Third intervention group:On the first day of lactation Infants weighing less than 1000 grams receive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams receive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams receive More volume based on their tolerance every 2-3 hours through gavage. After the first day,lactation increases by 10-20 cc/ kg /day and up to 200-100 cc /kg / day.In this group, when the amount of milk received reached 100 cc kg / day, the interventions begin. in this way 4.4 g of the supplement of aptamil FMS ( NUTRICIA) is dissolved in each 100 cc of breast milk and it is given to the infant based on the amount of milk received by the infant per day through gavage .it contains 1 g of protein, 0g of fat, 2.7g of carbohydrate and a certain amount of some salts and vitamins.Breast milk enrichment continues for up to 4 weeks after birth of some salts and vitamins.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Hajar Hospital

#### Full name of responsible person

Hadi Lachinani

#### Street address

Hajar Hospital,Nursing Street ,Kashan Blvd,Shahrekord City,Chahar Mahal and Bakhtiari

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۶۷۵۴۶۳۳

#### Phone

+98 38 3222 0016

#### Email

Hajar-Hospital@skums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Dr. seyed Kamal Solati

##### Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8815713471

##### Phone

+98 38 3334 2414

##### Email

kamal\_solati@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Majid Hamidi  
**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
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Shahrekord University of Medical Sciences, Building  
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majid.hamidi@yahoo.com

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
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Majid Hamidi

**Position**  
Assistant Professor  
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**Email**  
majid.hamidi@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

data will be kept private.

### Study Protocol

No - There is not 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

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Information about the main outcome can be shared.

### When the data will become available and for how long

Start the access period 4 months after printing the results

### To whom data/document is available

Researchers working in academia

### Under which criteria data/document could be used

Use data to complete fundamental studies

### From where data/document is obtainable

Hajar Hospital in Shahrekord,  
hadilachinanimd@gmail.com

### What processes are involved for a request to access data/document

after deliberation of researcher request and presentation of adequate documents, it will be able to exhibit.

### Comments