Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 recive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams recive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams recive 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 Ansaripour
Name of organization / entity
Shahrekord University of Medical Sciences
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Iran (Islamic Republic of)
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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 entery 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 recive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams recive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams recive 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 recive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams recive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams recive 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 recive 0.5-1 cc / kg breast milk every hour, Infants 1000 to 1500 grams recive 2-3 cc / kg breast milk every two hours and Infants weighing over 1600 grams recive 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 birthount 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

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

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Province

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8815713471

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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
Street address
Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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 delibration of researcher request and presentation of adequate documents,it will be able to exhibite.
Comments