Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluating the effect of increasing the amount of milk protein content by protein supplement on growth indices of preterm infants

Protocol summary

Study aim
Evaluating the effect of increasing the amount of milk protein content by protein supplement on growth indices of preterm infants

Design
A concealed, randomized, blinded, clinical trial with a parallel group design of 30 patients, enrolled between March 2014 and March 2015. ّ

Settings and conduct
The study was conducted at Imam Khomeini Hospital's NICU in Tehran. Newborns were randomly divided into two groups. By enteral feeding beginning we have added protein supplement to reach 4 grams per kilogram per day as total protein receiving per day which compare to the Control group who has taken 3.5 grams per kilogram per day protein with their enteral feeding. Its effects on neonatal growth indices, days of hospitalization, full fed time were recorded. Double-blinded study, which the patients, the nurses, the conductors, and the analyst _who later joined the research team and was not a member initially _ were not aware.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age less than 34 weeks; Birth weight less than 1500 grams. Exclusion criteria: Growth affecting anomalies; Parents disapproval; Unable to continue feeding for more than 72 hours; Urea over than 60 milligram per deciliter

Intervention groups
Participant in intervention group are premature infants born < 32 complete week's gestational and birthweight les than 1500 gram who will receive high protein diet, reaching the goal of 4 grams per kilogram per day. Participant in intervention group are also premature infants born < 32 complete week's gestational and birthweight les than 1500 gram who will receive standard protein diet which is 3.5 grams per kilogram per day. All participants' growth indices, days of hospitalization and full fed time were recorded.

Main outcome variables
Growth indices; Length of hospitalization; Oral tolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141118019991N3**
Registration date: **2021-09-16, 1400/06/25**
Registration timing: **retrospective**

Last update: **2021-09-16, 1400/06/25**
Update count: **0**

Registration date
2021-09-16, 1400/06/25

Registrant information

Name
Saharnaz Talebiyan

Name of organization / entity
Tehran university of medical science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
TEHRAN UNIVERSITY OF MEDICAL SCIENCE

Expected recruitment start date
2014-03-20, 1392/12/29

Expected recruitment end date
2015-03-20, 1393/12/29

Actual recruitment start date
2014-03-20, 1392/12/29

Actual recruitment end date

2015-03-20, 1393/12/29

Trial completion date

2015-03-20, 1393/12/29

Scientific title

Evaluating the effect of increasing the amount of milk protein content by protein supplement on growth indices of preterm infants

Public title

Effect of increasing the amount of milk protein content by protein supplement on growth indices of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age less than 34 weeks Birth weight less than 1500 grams No anomalies which affect on growth

Exclusion criteria:

Parents disapproval Unable to continue feeding more than 72 hours Urea over than 50 milligram per deciliter

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We will Use permuted block randomization and assign participants 1:1 to the standard of care diet (control) or higher protein Diet (intervention). Twins will be randomized individually. The study biostatistician will generate the allocation sequence and place the research assignments in envelopes, to be opened by research assistants on the study start date.

Blinding (investigator's opinion)

Double blinded

Blinding description

Parents, clinical staff, and all study staff apart from the research assistants who prepare the study diet will be blinded to the study group. Unblinding will be permitted if an error in milk preparation is identified, or if unexpected safety concerns arise that require unblinding.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2016-01-30, 1394/11/10

Ethics committee reference number

IR.TUMS.REC.1394.1781

Health conditions studied

1

Description of health condition studied

Very Low Birth Weight

ICD-10 code

P07.00

ICD-10 code description

Extremely low birth weight newborn, unspecified weight

Primary outcomes

1

Description

Weight

Timepoint

Daily from the first day of life

Method of measurement

Digital scale

2

Description

Height

Timepoint

Weekly from the first day of life

Method of measurement

meter

3

Description

Head Circumference

Timepoint

Weekly from the first day of life

Method of measurement
meter

Secondary outcomes

1

Description
Urea
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests (gr/dl)

2

Description
Bicarbonate
Timepoint
Biweekly
Method of measurement
Blood Sample enzymatic auto-analyzer

3

Description
Calcium
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests (mg/dl)

4

Description
Phosphorus
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests (mg/dl)

5

Description
Alkaline phosphatase
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests

6

Description
Albumin
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests

7

Description
Total protein
Timepoint
Biweekly
Method of measurement
Blood Sample Enzymatic tests (gr/dl)

8

Description
Clinical and Para-clinical sign of Necrotizing Enterocolitis
Timepoint
Multiple clinical Evaluation per day, and if needed also Para-clinical evaluation
Method of measurement
Clinical and Para-clinical Signs and symptoms.

9

Description
Sepsis Early or Late Onset, clinical or Para-clinical Sign and Symptoms.
Timepoint
Multiple clinical Evaluation per day, and if needed also Para-clinical evaluation
Method of measurement
Clinical and Para-clinical Signs and Symptoms

10

Description
Hospitalization Duration
Timepoint
Hospitalization Duration by days number at discharge.
Method of measurement
Hospitalization Duration days

Intervention groups

1

Description
Intervention group: High protein diet (4 grams per kilogram per day) which is provided by protein supplement, when the enteral feeding has been started.
Category
Treatment - Other

2

Description
Control group: Routine protein diet (3.5 grams per kilogram per day) which is provided by protein supplement, when the enteral feeding has been started.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Breastfeeding research center Tehran university of

medical sciences

Full name of responsible person
Saharnaz Talebiyan

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Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vice-Chancellor in Research Affairs

Street address
6th floor, Central University Organization, Qods Street, Keshavarz Boulevard

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Phone
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Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Saharnaz Talebiyan

Position
Consultant

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Position
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Person responsible for updating data

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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
No more information.
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable