

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

Growth indices; Length of hospitalization; Oral tolerance

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 less 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 less 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

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)

Phone

+98 21 6119 2407

Email address

s_talebiyan@yahoo.com

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 Squire, 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

Street address

Imam Khomeini Hospital Complex, Tohid Squire,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 2274 9212

Email

s_talebiyan@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8163 3698

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

Street address

Vali-asr hospital, Imam Khomeini Hospital Complex,
Tohid Squire

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 2274 9212

Fax

Email

s_talebiyan@yahoo.com

Web page address

Person responsible for scientific 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

Street address

Vali-asr hospital, Imam Khomeini Hospital Complex,
Tohid Squire

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 2274 9212

Fax

Email

s_talebiyan@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Vali-asr hospital, Imam Khomeini Hospital Complex,
Tohid Squire

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 2274 9212

Fax**Email**

s_talebiyan@yahoo.com

Web page address**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