Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of protein supplementation on growth of infants weighing less than 1000 g hospitalized in the neonatal intensive care unit Akbar Abadi Hospital in Tehran, in 2014- 2015

Protocol summary

Summary

Infants with birth weight less than 1000 g hospitalized in NICU in Akbarabadi Hospital, Tehran, Iran are being screened according to inclusion criteria untill n=32. By using blocking method, infants are divided into 2 groups of receiving protein supplements (Aptamil protein supplement) and receieving no protein diet. Concealment is in a way that the method of intervention is not disclosed until it is performed. This is a double-blind study (patient and analizer). Infants in control group with 100-120 kcal/kg/day receive enteral feeding evey 2-3 hours. Calorie intake is adjusted according to daily weight gain. In treatment group receiving protein, 0.6-0.8 gr/kg/day protein supplement is added to daily milk and is adjusted according to daily weight gain and weekly measurment of BUN, Cr, and Alb. The amount of receieved protein and calorie intestinally for each infant is calculated and recorded. Daily nutritional data are recorded until infant’s weight reaches 1500 g. The increase of BUN and the mean increase of necrotizing enterocolitis as a consequence of protein supplement in control group are compared with those of treatment group. Primary outcome: daily measurment of weight, weekly measurment of height and head circumference to assess infant growth Secondary outcomes: The incidence of morbidity, such as necrotizing enterocolitis, and increased kidney load as a result of increased BUN and Cr are recorded.

General information

Acronym

Protein supplementation, very low birth weight

IRCT registration information

IRCT registration number: **IRCT2016013126115N2**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name

Mandana Kashaki

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Faculty of Medicine, Iran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of protein supplementation on growth of infants weighing less than 1000 g hospitalized in the neonatal intensive care unit Akbar Abadi Hospital in Tehran, in 2014- 2015

Public title

The effect of protein supplementation on growth of infants weighing less than 1000 g hospitalized in the neonatal intensive care unit Akbar Abadi Hospital in Tehran, in 2014-2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion citeria: infants with birth wieght less than 1000 g who recieve 100-120 cc/kg/day milk and their parenteral feeding discontinued; infants with major congenital abnormalities, confirmed or suspected necrotizing enterocolitis before recieving protein supplements; infants who do not require a major surgery; infants without intrauterine infections that inhibit growth, or genetic diseases that lead to poor growth. Exclusion criteria: if BUN exceedes 25 or necrotizing enterocolitis symptoms appear or we have to NPO the newborn baby due to medical conditions, s/he will be excluded.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat High way

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.IUMS.REC.1394.9311165002

Health conditions studied

1

Description of health condition studied

Very low birth weight

ICD-10 code

P07.0

ICD-10 code description

Extremely low birth weight

Primary outcomes

1

Description

Head circumference

Timepoint

weekly until neonates weight get to 1500 gram.

Method of measurement

meter

2

Description

Weight

Timepoint

weekly until neonates weight get to 1500 gram.

Method of measurement

Scale

3

Description

Height

Timepoint

weekly until neonates weight get to 1500 gram.

Method of measurement

Meter

Secondary outcomes

1

Description

Neonatal entrocolitis

Timepoint

when neonates weight get to 1500 gram.

Method of measurement

Clinical examination

2

Description

Blood urea nitrogen

Timepoint

when neonates weight get to 1500 gram.

Method of measurement

Blood test

3

Description
Creatinine
Timepoint
when neonates weight get to 1500 gram.
Method of measurement
Blood test

Intervention groups

1

Description
In intervention group protein supplement to 0.8-0.6 gr / kg / day is added to milk daily and based on the daily weight gain and check of BUN, Cr and Alb is set on a weekly basis until the weight of nenonates get 1500 grams.
Category
Treatment - Other

2

Description
In infants in the control group kcal / kg / day 100-120 divided done every 2 to 3 hours enteral nutrition. Based on the amount of calories daily weight gain is adjusted.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar Abadi Hospital
Full name of responsible person
Street address
Shahid Akbar Abadi hospital, Ferdowsi Station, Molavi st.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Medicine, Iran University of Medical Sciences
Full name of responsible person
Leili Irani
Street address
Iran University of Medical Sciences, Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Medicine, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Zahra Behnamfar
Position
MD, Pediatrics resident
Other areas of specialty/work
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Name of organization / entity
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Mandana Kashaki
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Person responsible for updating data

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Name of organization / entity
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Position
Md, Pediatrics resident

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty