

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 until n=32. By using blocking method, infants are divided into 2 groups of receiving protein supplements (Aptamil protein supplement) and receiving 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 analyzer). Infants in control group with 100-120 kcal/kg/day receive enteral feeding every 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 measurement of BUN, Cr, and Alb. The amount of received 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 measurement of weight, weekly measurement 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)

###### Phone

+98 21 5563 2277

###### Email address

kashakimd@gmail.com

##### 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 criteria: infants with birth weight less than 1000 g who receive 100-120 cc/kg/day milk and their parenteral feeding discontinued; infants with major congenital abnormalities, confirmed or suspected necrotizing enterocolitis before receiving 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 exceeds 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 enterocolitis

##### **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 neonates 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

##### Street address

23 unit, Yasaman avn., Beheshti complex, Babaei highway

##### City

Tehran

##### Postal code

##### Phone

+98 21 7711 8969

##### Fax

##### Email

z\_behnamfar@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Akbar Abadi hospital

##### Full name of responsible person

Mandana Kashaki

##### Position

Assistant professor

##### Other areas of specialty/work

##### Street address

Shahid Akbar Abadi hospital, Ferdowsi Station, Molavi st.

##### City

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##### Phone

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kashakimd@gmail.com

##### Web page address

## Person responsible for updating data

### 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****Street address**

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**City**

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**Postal code****Phone**

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**Fax****Email**

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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*