

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Study of varying protein supplement effect on the growth criteria and maturation of immune system in very low birth weight infants .

#### Protocol summary

##### Summary

(1)Objectives: Varying Protein Supplement Effect on the Growth Criteria and Maturation of Immune System in very low birth weight infants . (2) Design:This study was a randomize trail and doubl blind on the preterm infant(w<1500 ,GA<32 w)admitted in NICU. target sample size was 30 in 3 equal groups.group A(intervention 1),group B(intervention 2) and group c(control group) (3) Setting and conduct: In special volume of breast milk protein supplement with varreing special doses added to breast milk and studing weight(daily), head circumference and length(weekly),WBC, neutrophil, lymphocyte ,IgG ,IgM and IgA(pre and post of study). (4) Participants including major eligibility criteria:Enclusion criteria containing Preterm infant with w<1500 gr and gestational age<32 weeks that admit in NICU (hajar hospital) from desember 2015 until may 2016 to feed whit riched milk by fortified. Exclusion criteria containing congenital malformations,NEC,major surjery, intera uteriane infections,koromosomal disorders and sepsis. (5) Intervention:Added protein supplement powder whit varying dose to breast milk in studding infants. (6) main outcome measures :Growth criteria contain weight,head circumference and length and immune system development criteria contain WBC, neutrophile, lymphocyte,IgG,IgM and IgA were primary and BUN and PH were secondary outcome variables.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041927474N1**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-21, 1395/03/01

##### Registrant information

###### Name

Elaheh Saghaei Dehkordi

###### Name of organization / entity

Shahrekord University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3224 1508

###### Email address

m.hamidi@skums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research,Shahrekord University Of Medical Sciences

##### Expected recruitment start date

2015-12-21, 1394/09/30

##### Expected recruitment end date

2016-05-21, 1395/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of varying protein supplement effect on the growth criteria and maturation of immune system in very low birth weight infants .

##### Public title

Protein supplement effect on the growth and immune system in preterm infants .

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Preterm infant with w<1500 gr and gestational age<32 weeks that admit in NICU (Hajar Hospital) from Desember 2015 until May 2016. Exclusion criteria: Congenital malformations; NEC; Major surgery; Intra uterian infections; Koromosomal disorders; Sepsis.

### **Age**

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

### **Gender**

Both

### **Phase**

0

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **30**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

table of random numbers

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shahrekord University Of Medical Sciences

##### **Street address**

Rahmatieh .Shahrekord University Of Medical Sciences.Ethics committee

##### **City**

Shahrekord

##### **Postal code**

##### **Approval date**

2016-01-31, 1394/11/11

##### **Ethics committee reference number**

IR.SKUMS.REC.1394.168

## **Health conditions studied**

### 1

#### **Description of health condition studied**

growth and immune disorders in preterm infants

#### **ICD-10 code**

XVI

### **ICD-10 code description**

P05,P07

## **Primary outcomes**

### 1

#### **Description**

Weight

#### **Timepoint**

Pre intervention and daily to end of intervention

#### **Method of measurement**

Digitaly scale /gram

### 2

#### **Description**

Head circumambient

#### **Timepoint**

Pre intervention,first and second week and end of intervention

#### **Method of measurement**

Non elastic meter/cm

### 3

#### **Description**

Length

#### **Timepoint**

Pre intervention,first and second week and end of intervention

#### **Method of measurement**

Non elastic meter/cm

### 4

#### **Description**

Neutrophil cell count

#### **Timepoint**

Pre and post intervention

#### **Method of measurement**

cbc.diff %

### 5

#### **Description**

Lymphocyte

#### **Timepoint**

Pre and post intervention

#### **Method of measurement**

cbc.diff %

### 6

#### **Description**

IgG

#### **Timepoint**

Pre and post intervention

#### **Method of measurement**

ELISA/mg/dl

## 7

### Description

IgM

### Timepoint

Pre and post intervention

### Method of measurement

ELISA/mg/dl

## 8

### Description

IgA

### Timepoint

Pre and post intervention

### Method of measurement

ELISA/mg/dl

## Secondary outcomes

### 1

#### Description

PH

#### Timepoint

Pre intervention, first and second week and post intervention

#### Method of measurement

ABG/m. mol

### 2

#### Description

BUN

#### Timepoint

Pre intervention, first and second week and post intervention

#### Method of measurement

BLOOD SAMPLE/mg/dl

## Intervention groups

### 1

#### Description

Intervention group 1: added protein supplement (4.8 mg/kg/day) from Aptamil company in 100 cc breast milk and used daily for 21 days. This supplement contains whey and casein protein.

#### Category

Other

### 2

#### Description

Intervention group 2: added protein supplement (3.5 mg/kg/day) from Aptamil company in 100 cc breast milk and used daily for 21 days. This supplement contains whey and casein protein.

#### Category

Other

## 3

### Description

Control group without any supplement and placebo

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahrekord Hajar Educational Hospital. NICU unit

##### Full name of responsible person

Elaheh Saghaei Dehkordi /Resident of pediatrics /Shahrekord University Of Medical Sciences

##### Street address

Parastar Street

##### City

Shahrekord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Dr Seyed Mohammad Omrani Vice Chancellor for research of Shahrekord University Of Medical Sciences

##### Full name of responsible person

Dr Seyed Mohammad Omrani Vice Chancellor for research, Shahrekord University Of Medical Sciences

##### Street address

Rahmatie Vice Chancellor for research of Shahrekord University Of Medical Sciences

##### City

Shahrekord

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Dr Seyed Mohammad Omrani Vice Chancellor for research of Shahrekord 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**

Shahrekord University Of Medical Sciences

**Full name of responsible person**

Dr Majid Hamidi

**Position**

Pediatrician/Scientific aspect member of Shahrekord University Of Medical Sciences

**Other areas of specialty/work****Street address**

Parastar Street.Hajar Hospital

**City**

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+98 38 3222 0016

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahrekord University Of Medical Sciences

**Full name of responsible person**

Dr Majid Hamidi

**Position**

Pediatrician

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahrekord University Of Medical Sciences

**Full name of responsible person**

Elaheh Saghaei Dehkordi

**Position**

Pediatric resident of Shahrekord University Of Medical Sciences

**Other areas of specialty/work****Street address**

Parastar Street.Hajar Hospital

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**Postal code****Phone**

+98 38 3222 0016

**Fax****Email**

elaheh.saghaei.80@gmail.com

**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*