

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

Shahrekord

Postal code**Phone**

+98 38 3222 0016

Fax**Email**

M.hamidi@skums.ac.ir

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

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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