Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Enclusion criteria:Preterm infant with w<1500 gr and gestional age<32 weeks that admit in NICU (Hajar Hospital) from Desember 2015 until May 2016. Exclusion critaria:Congenital malformations; NEC; Major surjery; 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 day. this supplement contain 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 day. this supplement contain 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 Unoversity 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
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 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
City
Shahrekord
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