

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the effects of synbiotic supplementation on weight gain, fecal ph, acetate, lactate, calprotectin in preterm infants

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

The aim of this study was to evaluate the effect of Lactobacillus plantarum and fructooligosaccharides on weight gain, change the pattern of enteric fermentation and intestinal inflammation in preterm infants in the neonatal intensive care unit in Kamali Hospital of Karaj. Inclusion criteria: all premature infants hospitalized in Kamali Hospital of Karaj and exclusion criteria: in the case of clinical symptoms of Sepsis (including severe lethargy, inability to feed, frequent vomiting, impaired consciousness, seizures, severe abdominal distention, laboratory findings such as positive blood culture and elevated CRP) or critically ill patient for any reason. After determining the population under study, infants were randomly divided into 4 groups: Symbiotic group: this group will received 5 drops of milk fortified with 108 Colony Forming Unit per ml (cfu/ml) of Lactobacillus plantarum and 0.8 grams per dL fructooligosaccharides twice a day for two weeks, probiotics group: this group will received 5 drops of milk fortified with 108 cfu/ml of Lactobacillus plantarum twice a day for two weeks, prebiotic group: this group will received 5 drops of milk fortified with 0.8 grams per dL fructooligosaccharides twice a day for two weeks, control group: this group will received regular milk twice a day for 2 weeks. After two weeks, anthropometric indices including height and weight of babies will be recorded. Also biochemical markers of colonization of probiotic bacteria include acetate, lactate and calprotectin in the stool of infants will be measured. The results of each group will be compared with control and statistically analyzed.

Last update:

Update count: **0**

Registration date

2016-07-04, 1395/04/14

Registrant information

Name

Mahboobeh Mehrabani Natanzi

Name of organization / entity

Alborz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6008

Email address

mahboobehmehrabani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research (Alborz University of Medical Sciences)

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of synbiotic supplementation on weight gain, fecal ph, acetate, lactate, calprotectin in preterm infants

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016061128386N1**

Registration date: **2016-07-04, 1395/04/14**

Public title

Evaluation of the effects of synbiotic supplementation on weight gain, fecal ph, acetate, lactate, calprotectin in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Infants weighing less than 2500 g or 37 week; all premature infants hospitalized in Kamali Hospital of Karaj Exclusion criteria: in the case of clinical symptoms of Sepsis (including severe lethargy, inability to feed, frequent vomiting, impaired consciousness, seizures, severe abdominal distention, laboratory findings such as positive blood culture and elevated CRP); critically ill patient for any reason.

Age

To 14 days old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Sciences

Street address

Faculty of medicine, Golestan 1, Eshteraki, Baghestan, Karaj

City

Karaj

Postal code

Approval date

2016-05-02, 1395/02/13

Ethics committee reference number

abzums.Rec.1395.2

Health conditions studied

1

Description of health condition studied

Preterm infants

ICD-10 code

P78.9

ICD-10 code description

Digestive system disorders of fetus and newborn

Primary outcomes

1

Description

Body Weight

Timepoint

14 days

Method of measurement

weightening for body weight

2

Description

Fecal lactate

Timepoint

14 days

Method of measurement

GC-MASS

3

Description

Fecal calprotectin

Timepoint

14 days

Method of measurement

ELISA kit

4

Description

Fecal acetate

Timepoint

14 days

Method of measurement

GC-MASS

Secondary outcomes

1

Description

Duration of hospitalization in

Timepoint

day of discharge from hospital

Method of measurement

Counting days

Intervention groups

1

Description

Intervention group 1: this group will received 5 drops of milk fortified with 108 Colony Forming Unit per ml (cfu/ml) of Lactobacillus plantarum and 0.8 grams per dL fructooligosaccharides twice a day for two weeks

Category

Treatment - Drugs

2

Description

Intervention 2: this group will received 5 drops of milk fortified with 108 cfu/ml of Lactobacillus plantarum twice a day for two weeks

Category

Treatment - Drugs

3

Description

Intervention 3: this group will received 5 drops of milk fortified with 0.8 grams per dL fructooligosaccharides twice a day for two weeks

Category

Treatment - Drugs

4

Description

Control group: this group will received regular milk twice a day for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Dr Arezo Hemati

Street address

Kamali Hospital, Shohada square, Karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Alborz University of Medical Sciences

Full name of responsible person

Dr Mohammad Javad Gharavi

Street address

Dara Building, East Pooneh, 45 meters Golshahr, Karaj

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Mahboobeh Mehrabani Natanzi

Position

PhD in biochemistry

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Zohreh Khodaii

Position

PhD in nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
khaterh Amini
Position
MSC of food industry
Other areas of specialty/work
Street address
Dara Building, East Pooneh, 45 meters Golshahr,
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City
Karaj

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