Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of probiotics on intestinal feeding tolerance in preterm infants hospitalized in 17 shahrivar hospital of Rasht

Protocol summary

Summary

Objectives :To assess the effect of probiotics on intestinal feeding tolerance in preterm infants hospitalized in 17 Shahrivar hospital of Rasht, Design: A double blind controlled clinical trial, Participants including major eligibility criteria: 68 preterm infants with gestational age less than 36 weeks and 1000 - 2500 gram birth weight. Neonates with congenital malformations will be excluded from the study, Intervention: Eligible neonates will be assessed in two groups of treatment (oral probiotics) and control (normal saline), main outcome measures (variables): Mean duration of reaching full enteral feeding will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706129075N2**
Registration date: **2017-09-11, 1396/06/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-11, 1396/06/20

Registrant information

Name

Seyyedeh Zohreh Jalali

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

The Vice Chancellor of Research of Guilan University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-04-01, 1397/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of probiotics on intestinal feeding tolerance in preterm infants hospitalized in 17 shahrivar hospital of Rasht

Public title

Assessing the effect of probiotics on intestinal feeding tolerance in preterm infants hospitalized in 17 shahrivar hospital of Rasht

Purpose

Supportive

Inclusion/Exclusion criteria

Main inclusion criteria: Preterm infants with gestational age less than 36 weeks; Birth weight between 1000 and 2500 gram; Age less than or equal to two weeks with enteral feeding. Main exclusion criteria: Neonates with congenital malformations (congenital heart diseases; gastrointestinal obstruction; omphalocele; gastroschisis); congenital metabolism errors; Grade two and three of asphyxia; newborns of addicted mothers; age more than two weeks.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
Gaz Square
City
Rasht
Postal code
Approval date
2017-04-29, 1396/02/09
Ethics committee reference number
IR.GUMS.REC.1396.40

Health conditions studied

1

Description of health condition studied
preterm birth
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Mean duration of reaching full enteral feeding
Timepoint
at the discharge
Method of measurement
day

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, administering oral probiotics with a dose of 1 drop/ kg diluted with up to 0.5 cc saline solution
Category
Rehabilitation

2

Description
In the control group, 0.5 cc of the normal saline solution will be administered every 12 hours and will be continued to reach 120 cc / kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Hospital
Full name of responsible person
Dr Seyyedeh Zohre Jalali
Street address
Siadati Street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Vice Chancellor of Resrach of Guilan niversity of Medical Sciences
Full name of responsible person
Dr Shadman Nemati
Street address
Gaz Square
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Vice Chancellor of Resrach of Guilan niversity 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
Guilan University of Medical Sciences
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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