Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of probiotics on prevention of necrotizing enterocolitis in preterm infants

Protocol summary

Study aim
Determination of the effect of probiotics on prevention of necrotizing enterocolitis in preterm infants

Design
This randomized clinical trial will be conducted on preterm infants with low birth weight and very low birth weight. The study will be blinded in triplicate. 100 neonates in the number of 50 neonates in the intervention group and 50 neonates in the control group will be placed in the matched numbered envelopes and will be labeled. From a group of patient researchers who collects patient information, the parents of the infant and the collaborator of the project that will perform the statistical analysis will not be informed (blind trivial)

Settings and conduct
This study was performed to evaluate the effect of probiotic on NEC in preterm infants. 64 preterm infants were divided into two intervention and control groups from birth and the study was three-way blind. And in Imam Reza Hospital in neonatal intensive care unit

Participants/Inclusion and exclusion criteria
Inclusion criteria: VLBW infants (gestational age ≤ 34 weeks and birth weight ≤ 1500 g) survive until the onset of oral nutrition. Exclusion criteria: 1. Severe asphyxia (stage III) 2. Congenital major anomalies 3. Babies who have not started oral feeding for 3 weeks after birth. 4. Infants receiving antifungal treatment.

Intervention groups
The intervention group consisted of newborn infants with probiotic podilakat made by Iran Fertilizer Company in a quantity of 1 drops per kg of weight every 12 hours with breast milk or milk powder. The control group is a neonate who will receive 0.5 cc normal saline every 12 hours with breastfeeding or breastfeeding.

Main outcome variables
Baby weight at the end of the third month

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170121032075N2**
Registration date: **2019-07-29, 1398/05/07**
Registration timing: **retrospective**

Last update: **2019-07-29, 1398/05/07**
Update count: **0**

Registration date
2019-07-29, 1398/05/07

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 912 619 4166
Email address
mirmohammadif951@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-08-23, 1396/06/01
Expected recruitment end date
2018-03-21, 1397/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of probiotics on prevention of

necrotizing enterocolitis in preterm infants

Public title
The effect of probiotics on prevention of necrotizing enterocolitis in neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
VLBW infants (gestational age ≤ 34 weeks and birth weight ≤ 1500 g) survive until oral nutrition begins.
Exclusion criteria:
Severe asphyxia (stage III) Congenital major anomalies Babies who have not started oral feeding for 3 weeks after birth Infants receiving antifungal treatment
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was carried out simply. The allocation of newborns to the intervention and control groups is as follows: the study population will be randomly selected by computer. This study will be blinded in triplicate. Based on the randomization table arranged by the computer, the intervention and control group will be placed inside the matched envelopes and will be inserted.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The researcher, parents and the collaborator of the project who will perform the statistical analysis will not be aware of the study . grouping of patients will be noted and will be shared to one of the partners
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreyshi Bul- daneshgah Ave- Mashhad University of medical sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2018-05-23, 1397/03/02
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.067

Health conditions studied

1

Description of health condition studied
Necrozen enterocolitis is the most common gastrointestinal emergency in premature infants
ICD-10 code
A04.7
ICD-10 code description
Enterocolitis due to Clostridium difficile

Primary outcomes

1

Description
birth weight
Timepoint
before intervention in time of birth
Method of measurement
Kilogram

Secondary outcomes

1

Description
weight
Timepoint
after intervention
Method of measurement
Kilogram

Intervention groups

1

Description
Intervention group: The infants received podilactok probiotics in a dose of 1 drops per kg of body weight every 12 hours with breast milk or milk powder .
Category
Treatment - Drugs

2

Description
Control group: The control group received 0.5 cc normal saline every 12 hours along with a type of infant or breast milk
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Mir Farhad Mirmohammadi
Street address
Ibn Sina Ave- Imam Reza Hospital - Mashhad- Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mir Farhad Mirmohammadi
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Daneshgah Ave- Ghoreyshi bul- Mashhad University of medical sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mir Farhad Mirmohammdi
Position
Neonatologist
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ibn sina Ave- Imam Reza hospital- Mashhad- Iran
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Person responsible for updating data

Contact

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Full name of responsible person
Mir Farhad Mirmohammadi

Position
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Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
En A part of the questionnaire information that relates to patient information is shared.

When the data will become available and for how long
Start the access period after printing the results

To whom data/document is available
Available to academic and academic researchers

Under which criteria data/document could be used
After publishing it as a paper for the public and researchers from academic medical institutions

From where data/document is obtainable
ISI and Google

What processes are involved for a request to access data/document
In search sites, the use of Probiotics, Preterm newborn, Necrotizing enterocolitis

Comments