Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of probiotics on intestinal colonization of pathogenic bacteria and Candida in very low birth weight premature infants admitted to the neonatal intensive care unit.

Protocol summary

Study aim

Determining the role of probiotics in bacterial and candida intestinal colonization in very low birth weight premature infants admitted to the neonatal intensive care unit

Design

A controlled clinical trial with parallel groups, without blinding, randomized, on 130 patients. The rand function of Excel software was used for randomization.

Settings and conduct

A single-center, unblinded, randomized trial in the neonatal intensive care unit (NICU). VLBW infants receive either the probiotic *Lactobacillus reuteri* or no intervention for 5 days. Stool samples are examined for pathogen colonization on day 6. Families and physicians are unaware of the type of grouping. The study will be conducted at Shahid Motahari Hospital, Urmia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants with low birth weight (birth weight between 1000 and 1500 grams) Gestation age less than 32 weeks Admission to the neonatal intensive care unit (NICU) in the first 72 hours of life Exclusion criteria: Patient's parents' lack of consent Infant with digestive disorders after entering the study (intestinal obstruction, severe digestive diseases, etc.) Drug allergy Mortality

Intervention groups

Infants were randomly assigned to two control groups, which included two subgroups of breastfed infants and formula-fed infants, and probiotic recipients, which included two subgroups of breastfed infants And infants who are fed formula will be allocated. From the time of starting feeding, five drops of probiotic Lactobacillus reuteri (Procid) will be given to infants daily for 5 days. On the sixth day, the infants' stool will be collected

Main outcome variables

The primary outcome in this study is a comparison of intestinal colonization in the probiotic group compared to the control group. Secondary outcomes include stool exam.

General information

Reason for update

Acronym

PP-VLBW

IRCT registration information

IRCT registration number: **IRCT20171218037936N4**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date

2025-10-08, 1404/07/16

Registrant information

Name

Kamran Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3365 4154

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of probiotics on intestinal colonization of pathogenic bacteria and Candida in very low birth weight premature infants admitted to the neonatal intensive care unit.

Public title

Studying the effect of probiotics on intestinal colonization of pathogenic bacteria and Candida in very low birth weight premature infants admitted to the neonatal intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature, low birth weight (birth weight between 1000 and 1500 grams) Gestational age less than 32 weeks Admission to the neonatal intensive care unit (NICU) within the first 72 hours of life

Exclusion criteria:

Dissatisfaction of the patient's parents Infant with digestive disorders after entering the study (intestinal obstruction, severe digestive diseases, etc.) Drug allergy Mortality

Age

To **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be carried out using a computer-generated random number sequence created in Microsoft Excel (version ...), which will be executed by a research assistant not involved in participant recruitment or clinical care to ensure allocation concealment. Acknowledging the type of feeding as a significant and influential variable, the randomization process will be stratified based on two distinct strata: 'breastfed infants' and 'formula-fed infants'. Within each of these feeding strata, infants will be randomly allocated in a 1:1 ratio to either the intervention group, receiving the probiotic supplement, or the control group, receiving a placebo. This stratified randomization approach ensures a balanced distribution of infants with different feeding patterns across both study groups, thereby enabling a robust and valid comparison of the probiotic's effect.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Orzhans Alley, Resalat St. ,Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2025-09-24, 1404/07/02

Ethics committee reference number

IR.UMSU.REC.1404.285

Health conditions studied

1

Description of health condition studied

Intestinal Colonization by multidrug-resistant organisms and Candida species.

ICD-10 code

A04.9

ICD-10 code description

Bacterial intestinal infection, unspecified

Primary outcomes

1

Description

Rate of intestinal colonization with pathogenic bacteria based on stool culture

Timepoint

Day 6 after the start of the intervention

Method of measurement

Microbiological culture of stool sample

Secondary outcomes

1

Description
Results of the Stool Exam
Timepoint
Day 6 after the start of the intervention
Method of measurement
Direct microscopic examination of the stool sample

Intervention groups

1

Description
Intervention group: The probiotic group, which includes two subgroups of breastfed infants and formula-fed infants, will be assigned. From the start of feeding, five drops of probiotic Lactobacillus reuteri (Procid) will be given to the infants daily for 5 days.On the sixth day, the newborn's stool will be collected and sent to the laboratory of Shahid Motahari Hospital in Urmia for culture and stool examination.
Category
Prevention

2

Description
Control group: Includes two subgroups of breastfed infants and formula-fed infants. On the sixth day, the infants' stool will be collected and sent to the laboratory of Shahid Motahari Hospital in Urmia for culture and stool exam.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Motahhari Hospital
Full name of responsible person
Dr Kamran Dehghan
Street address
Motahhari hospital, Kashani Av Urmia West Azarbaijan Iran, Islamic Republic Of
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5714615463
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dr_kamrandehghan@yahoo.com
Web page address
http://www.motahari.umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Deputy for research of Urmia university of medical sciences, Jahad Ave. , Urmia, Iran.
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Fax
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Kamran Dehghan
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available