

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of dietary supplementation of probiotic *Lactobacillus reuteri* on gastrointestinal complications of enteral feeding in premature infants with low birth weight

Protocol summary

Summary

This is a triple blind randomized clinical trial was performed on 60 premature infants. The study population were preterm infants (34-28 weeks gestation), weighing 1800 to 1000 gr admitted in neonatal intensive care unit of the Shahid Sadoghi hospital's . 25 people numbers were calculated for each group of infants were randomly allocated to either the intervention group (taking a probiotic) or control (placebo). For the experimental group were given probiotic supplements orally every 12 hours at a rate of one drop per kilogram of body weight was diluted with 0.5 ml distilled water. For the placebo group was given 0.5 ml of distilled water every 12 hours. Treatment was continued until reaching full enteral feeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030716870N1**

Registration date: **2014-04-17, 1393/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-17, 1393/01/28

Registrant information

Name

Khadije Nasiriani

Name of organization / entity

Yazd Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1755

Email address

nasiriani@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Medical College of Ali Ibn Abeetaleb

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dietary supplementation of probiotic *Lactobacillus reuteri* on gastrointestinal complications of enteral feeding in premature infants with low birth weight

Public title

Effect of probiotic *Lactobacillus reuteri* on enteral feeding in premature infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: prematurity with birth weight 1000-1800 g. Exclusion criteria: digestive obstruction; abdominal distension; gastrointestinal bleeding; gastroschisis, omphalocele; withdrawal syndrome; clinical or proven sepsis; congenital heart diseases and II and III degree of asphyxia.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ali ibn Abi Talib College of Medicine

Street address

Professor Hesabi Blv, Medical College of Ali Ibn Abee,
Islamic Azad University, Yazd

City

Yazd

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

2883

Health conditions studied**1****Description of health condition studied**

Premature infant

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks

Primary outcomes**1****Description**

Enteral feeding hang time

Timepoint

Daily

Method of measurement

Daily milk volume of 120 ml / kg/day

Secondary outcomes

empty

Intervention groups**1****Description**

probiotic group was prescribed one 1 drop/kg probiotic supplemental orally with 0.5 ml distilled water every 12 hours.

Category

Treatment - Drugs

2**Description**

The placebo group was received 0.5 ml of distilled water every 12 hours and cure was continued to reach full enteral

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi Hospital

Full name of responsible person

Khadijeh Nasiriani

Street address

School of Nursing & Midwifery, Buali street, Safaieh,
Yazd

City

Yazd

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ali ibn Abi Talib College of Medicine

Full name of responsible person

Dr. Shajari

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Professor Hesabi Blv, Medical College of Ali Ibn Abee,
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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

Ali ibn Abi Talib College of Medicine

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**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

PhD in Nursing

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

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Position

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Nursing PhD

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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