

# 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

**Street address**

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

**City**

Yazd

**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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**Postal code****Phone**

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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**

Mahmood Noori-Shadkam

**Position**

Pediatrics/Associate Professor

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

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Khadijeh Nasiriani

**Position**

Nursing PhD

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nasiriani@gmail.com; nasiriani@ssu.ac.ir

**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*