

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of Probiotics in duration of treatment of neonatal jaundice with 42-37 weeks gestational age

#### Protocol summary

##### Summary

The design of an experimental study is to investigate the effect of probiotics on the duration of treatment of neonatal jaundice in gestational age of 37-42 weeks. Infants with infections, thyroid problems, and history of any blood product injection are excluded from the study. The study population was infants admitted to NICU1 and NICU2 in Kamali hospital, Karaj, Iran. The sample size was 45 in each intervention and control group. In the first step, the neonate bilirubin is checked using a serum sample in the laboratory. Then, they are randomly divided into two groups of intervention and control (paired up / individual). In the intervention group, 1 cc of probiotic lactoacidophilus is added to the two daily meals. Bilirubin is checked daily and recorded in a table. Then, the collected data are analyzed using statistical tests. Finally, the results are compared with the amount of bilirubin changes in the two groups, as well as the duration of hospitalization of these infants.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042733661N1**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-30, 1396/04/09

##### Registrant information

###### Name

Alireza Jashnimotlagh

###### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3222 2021

##### Email address

dr.jashnimotlagh@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Alborz University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Probiotics in duration of treatment of neonatal jaundice with 42-37 weeks gestational age

##### Public title

The effect of Probiotics in treatment of neonatal jaundice

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: gestational age (42-37 weeks); jaundice (physiological and non-physiological). Exclusion criteria: Infection; SEPSIS; Hypothyroidism; History the blood transfusion.

##### 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: 90

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Alborz University of Medical Science

##### Street address

Alborz University of Medical Science, Office Park,  
Taleghani Square, Azimieh

##### City

Karaj

##### Postal code

-

#### Approval date

2016-12-24, 1395/10/04

#### Ethics committee reference number

Abzums.rec.1395.48

## Health conditions studied

### 1

#### Description of health condition studied

Neonatal Jaundice

#### ICD-10 code

P00

#### ICD-10 code description

Newborn/ Neonatal Diagnoses

### 2

#### Description of health condition studied

Neonatal Jaundice

#### ICD-10 code

P96

#### ICD-10 code description

Newborn/ Neonatal Diagnosis

## Primary outcomes

### 1

#### Description

Neonatal Jaundice

#### Timepoint

Dqily

#### Method of measurement

Blood test

## Secondary outcomes

### 1

#### Description

Duration of treatment of Neonatal Jaundice

#### Timepoint

Discharge Time

#### Method of measurement

The number of days of hospitalization records

## Intervention groups

### 1

#### Description

Intervention group: 1 cc Probiotics will be added totwice of the milk of their daily milk( Lactobacillus with 10\*9 colonies).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali Hospital( Karaj)

##### Full name of responsible person

Dr. Alireza Jashnimotlsg

##### Street address

KAMALI Hospital,Kamali alley,Shahid Beheshti  
st,Shohada Squ,

##### City

Karaj

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Alborz University of  
Medical Sciences

##### Full name of responsible person

Alireza Jashnimotlagh

##### Street address

KAMALI Hospital,Kamali alley,Shahid Beheshti  
st,Shohada Squ,

**City**  
Karaj

**Grant name**  
-

**Grant code / Reference number**  
-

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Vice Chancellor for Research, Alborz University 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**  
*empty*

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Alborz University of Medical Science

**Full name of responsible person**  
Badri Farhand

**Position**  
Master of Neonatal Intensive Care Nursing

**Other areas of specialty/work**

**Street address**  
KAMALI Hospital,Kamali alley,Shahid Beheshti st,Shohada Squ,

**City**  
Karaj

**Postal code**  
3134877179

**Phone**  
+98 26 3222 2021

**Fax**  
-

**Email**  
Badrifarhand@yahoo.com

**Web page address**  
-

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Alborz University of Medical Science

**Full name of responsible person**  
Dr. Alireza Jashnimotlagh

**Position**

Neonatalogist Doctor

**Other areas of specialty/work**

**Street address**  
KAMALI Hospital,Kamali alley,Shahid Beheshti st,Shohada Squ,

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**Email**  
dr.jashnimotlagh@abzums.ac.ir

**Web page address**  
-

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Alborz University of Medical Science

**Full name of responsible person**  
Badri Farhand

**Position**  
Master of Neonatal Intensive Care Nursing

**Other areas of specialty/work**

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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*