

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

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

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Person responsible for scientific inquiries

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Full name of responsible person
Dr. Alireza Jashnimotlagh

Position

Neonatalogist Doctor

Other areas of specialty/work

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Person responsible for updating data

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Position
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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