

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of probiotics vs. placebo in decreasing hospitalization duration in infants with hyperbilirubinaemia: a randomized clinical trial

Protocol summary

Summary

The aim of the present study is to evaluate the effectiveness of probiotics in decreasing hospitalization duration in infants with hyperbilirubinaemia. So infants with gestational age of more than 35 weeks, birth weight more than 2500 gr and bilirubin level of more than 15 will be randomly assigned into two groups by a computer-generated randomization list; one with probiotics and other with placebo as well as common therapeutic methods like phototherapy. Afterward the effect of probiotics in decreasing hospitalization duration will be assessed in comparison with placebo. Septic and ill infants and those less than 2 days old will be excluded from study. Parents and nurse who was responsible for drug prescription were not informed about the ingredients of drugs and that which one are placebo and which ones are not.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021817413N11**

Registration date: **2015-09-16, 1394/06/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Deputy of Research

Expected recruitment start date

2015-07-10, 1394/04/19

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of probiotics vs. placebo in decreasing hospitalization duration in infants with hyperbilirubinaemia: a randomized clinical trial

Public title

Use of probiotics in icter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age of more than 35 weeks; birth weight of more than 2500 gr; serum level of bilirubin more than 15 mg/dL; direct bilirubin of less than 1.5 mg/dL. Exclusion criteria: Infants less than 2 days of age; ill and septic patients; infants with positive Coombs test; those undergoing blood exchange or IVIG and

phenobarbital therapy; patients needing serum therapy.

Age

From **2 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences, Ethics Committee

Street address

Baqiyatallah University of Medical Sciences, South Sheykh Bahaei, Mollasadra st., Vanaq sq., Tehran, IR Iran

City

Tehran

Postal code

Approval date

2015-04-11, 1394/01/22

Ethics committee reference number

IR.BMSU.REC.1394.87

Health conditions studied

1

Description of health condition studied

Physiologic Jaundice

ICD-10 code

p59.9

ICD-10 code description

Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description

Hospitalization duration

Timepoint

after beginning treatment till discharge

Method of measurement

Days Hospitalized after treatment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will be treated by a half capsule of Prokid probiotic once a day before breast feeding till discharge.

Category

Treatment - Drugs

2

Description

Control group: will use placebo, which is half capsule filled with probiotic-free formula with the same color as the Prokid probiotic, once a day before breast feeding till discharge.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohammad Torkaman

Street address

Baqiyatallah Hospital, Mollasadra st., Vanaq sq., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences, Deputy of Research

Full name of responsible person

Gholam Hossein Alishiri

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak

Square, Tehran, I.R.Iran.

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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

Baqiyatallah University of Medical Sciences, Deputy of Research

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

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

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Person responsible for scientific inquiries

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Full name of responsible person

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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