

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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)

##### Phone

+98 21 8126 4354

##### Email address

hrkarimisari@bmsu.ac.ir

##### 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

##### City

Tehran

## 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.

**City**

Tehran

**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**

General practitioner / Researcher

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

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

Department of Pediatrics, Baqiyatallah University of medical sciences

**Full name of responsible person**

Mohammad Torkaman

**Position**

Pediatrician

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

**Full name of responsible person**

Mohammad Hossein Khosravi

**Position**

General practitioner / Researcher

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

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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*