

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of phototherapy with and without probiotics on serum bilirubin level in term infants: a single-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of phototherapy with and without probiotics on serum bilirubin level in term infants

##### Design

This is a single-blind randomized clinical trial, phase II, in which 150 eligible infants will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible infants with neonatal jaundice who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single so that neonates will not be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 1 to 28 days, Healthy infant, Birth weight above 2500 g Exclusion criteria: Fetal age less than 37 weeks, Immunocompatibility of blood groups, Immunocompatibility of Rh, Glucose 6 phosphate dehydrogenase deficiency, First-day jaundice. Taking phenobarbital during pregnancy by the mother

##### Intervention groups

Intervention group: Routine phototherapy plus probiotic oral drop (Pedilact) made by Zist-Takhmir Company 10 drops daily for 3 days Control group: Just routine phototherapy

##### Main outcome variables

Primary outcome: Mean serum bilirubin level of infants

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N306**

Registration date: **2019-10-05, 1398/07/13**

Registration timing: **prospective**

Last update: **2019-10-05, 1398/07/13**

Update count: **0**

##### Registration date

2019-10-05, 1398/07/13

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of phototherapy with and without probiotics on serum bilirubin level in term infants: a single-blind randomized clinical trial

##### Public title

Effect of phototherapy with and without probiotics on serum bilirubin level in term infants

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age of 1 to 28 days, Healthy infant, Birth weight above 2500 g

**Exclusion criteria:**  
Fetal age less than 37 weeks, Immunocompatibility of blood groups, Immunocompatibility of Rh, Glucose 6 phosphate dehydrogenase deficiency, First day jaundice. Taking phenobarbital during pregnancy by the mother

**Age**  
From **1 day** old to **28 days** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **150**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Infants will not be aware of the type of intervention. Thus, the trial will be run as single-blind

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

**Postal code**  
6517838695

**Approval date**  
2019-09-14, 1398/06/23

**Ethics committee reference number**  
IR.UMSHA.REC.1398.458

## Health conditions studied

### 1

#### Description of health condition studied

Neonatal jaundice

#### ICD-10 code

P59.9

#### ICD-10 code description

Neonatal jaundice, unspecified

## Primary outcomes

### 1

#### Description

Mean serum bilirubin level of infants

#### Timepoint

Before the intervention and 2 and 3 days after the intervention

#### Method of measurement

By laboratory test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Routine phototherapy plus probiotic oral drop (Pedilact) made by Zist-Takmir Company 10 drops daily for 3 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Just routine phototherapy

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital in Hamadan City

##### Full name of responsible person

Soroush Taheri Talesh

**Street address**  
Besat Hospital, Shahed Square  
**City**  
Hamadan  
**Province**  
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**Postal code**  
6517838695  
**Phone**  
+98 81 3364 0030  
**Email**  
kopolak4@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Saeid Bashirian  
**Street address**  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave  
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+98 81 3838 0717  
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info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Soroush Taheri Talesh  
**Position**

Medical Student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Emergency Medicine

#### Street address

Besat Hospital, Shahed Square

#### City

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#### Province

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## Person responsible for scientific inquiries

#### Contact

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Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Fatemeh Eghbalian  
**Position**  
Podiatrist  
**Latest degree**  
Medical doctor  
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Pediatrics  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Jalal Poorolajal  
**Position**  
Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
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**Province**

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**Email**

poorolajal@umsha.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available