

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)

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+98 81 1838 0090

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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-Takhmir 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
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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

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

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Person responsible for updating data

Contact

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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