

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effect of prophylactic phototherapy with therapeutic phototherapy on serum bilirubin and neurodevelopment in 1500-2000-gr preterm neonates

#### Protocol summary

##### Study aim

Comparison of the effect of prophylactic phototherapy with therapeutic phototherapy on neurodevelopment among 1500-2000 gram preterm neonates born in Shohadaye Khalije Fars and Salman Farsi Hospitals in Bushehr in 2021-2022

##### Design

Clinical trial with control group, with parallel groups, single blind, randomized, on 200 patients. R software was used for randomization

##### Settings and conduct

Study place: Neonatal wards of Salman Farsi and Shohadaye Khalije Fars hospitals in Bushehr. Study population: All neonates under 37 weeks old weighing 1500-2000 grams hospitalized in the mentioned places. Blinding: One-way blinding. How to blind: Parents do not know if their baby is in the intervention group or the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants weighing 1500-2000 gram. Non-inclusion criteria: Dissatisfaction with participating in the study, asphyxia, cerebral hemorrhage, meningitis, neurological problems such as seizures without jaundice, structural brain problems, Hypoxia, sepsis (positive blood culture), ABO incompatibility, first-day jaundice

##### Intervention groups

Intervention group (A): Infants receive prophylactic phototherapy in the first 24 hours of birth. Control group (B): Infants do not receive prophylactic phototherapy in the first 24 hours of birth and receive phototherapy if bilirubin increases according to the curves in Nelson's book.

##### Main outcome variables

Direct bilirubin; Total bilirubin; Development

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211015052778N1**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

##### Registration date

2022-05-11, 1401/02/21

##### Registrant information

##### Name

Soroush Ostadzade

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3333 5250

##### Email address

soorena767@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of prophylactic phototherapy with therapeutic phototherapy on serum bilirubin and neurodevelopment in 1500-2000-gr preterm neonates

## Public title

Evaluation of phototherapy on premature neonates

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Premature infants weighing 1500-2000 gr

### Exclusion criteria:

Dissatisfaction with participating in the study  
Asphyxia  
Cerebral hemorrhage  
Meningitis  
Neurological problems such as seizures without jaundice  
Structural brain problems  
Hypoxia  
Sepsis (positive blood culture)  
ABO incompatibility  
First-day jaundice

## Age

To 4 months old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: 200

## Randomization (investigator's opinion)

Randomized

## Randomization description

Infants with  $\leq 1500-2000$  gr will be randomly divided into two groups. Random allocation was performed using R software and the resulting random design will be placed in special envelopes. Infants who meet the required criteria will be assigned to the intervention group (A) and the control group (B) consecutively. The random allocation file is attached in the appendices section. The intervening physician will not be aware of the random allocation scheme and the number of blocks.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Study participants do not know whether they are in the control or the intervention group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Boushehr University of Medical Sciences

## Street address

Bushehr University of Medical Sciences and Health Services, In front of Mosallaye Namaze Jome, Moallem St.

## City

Boushehr

## Province

Boushehr

## Postal code

7514633341

## Approval date

2021-05-19, 1400/02/29

## Ethics committee reference number

IR.BPUMS.REC.1400.024

## Health conditions studied

### 1

#### Description of health condition studied

Hyperbilirubinemia

#### ICD-10 code

E80.6

#### ICD-10 code description

Other disorders of bilirubin metabolism

## Primary outcomes

### 1

#### Description

Total bilirubin

#### Timepoint

Measurement of total blood bilirubin at the beginning of the study (before the intervention) and then on days 1, 3, 5, 7 and 10 after birth

#### Method of measurement

In Shohadaye Khalije Fars Hospital, the bilirubin samples will be tested based on photometric principles and using Jendrssiik Grof Assay kit from Biorex Fars Company through DIRUI CS-400 Auto-Chemistry Analyzer. In Salman Farsi Hospital, the bilirubin samples will be measured based on the same principles and kit used in the Shohadaye Khalije Fars Hospital using the DIRUI CS-400 Auto-Chemistry Analyzer.

### 2

#### Description

Development

#### Timepoint

2 and 4 month

#### Method of measurement

By ASQ questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: infants will receive prophylactic phototherapy in the first 24 hours after birth. Phototherapy will be performed using a 5-DTA-lamp portable Phototherapy Equipment - XHZ-90P with Philips lamps in Shohadaye Khalije Fars Hospital and using Tucson phototherapy device with Philips lamps in Social Security Hospital (Salman Farsi Hospital)

#### Category

Treatment - Devices

### 2

#### Description

Control group: receive no prophylaxis, and infants will receive therapeutic phototherapy after bilirubin rise according to the curves in Nelson's book.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Khalije Fars hospital

##### Full name of responsible person

Soroush Ostadzade

##### Street address

Taleghani Blvd

##### City

Boushehr

##### Province

Boushehr

##### Postal code

۷۵۱۷۹۳۳۷۵۵

##### Phone

+98 77 3345 5375

##### Email

mpgh@bpums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Salman Farsi hospital

##### Full name of responsible person

Soroush Ostadzade

##### Street address

Sabzabad Street

##### City

Boushehr

##### Province

Boushehr

##### Postal code

7518759416

##### Phone

+98 77 3344 2815

##### Email

salmanfarsi.hos@tamin.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Boushehr University of Medical Sciences

##### Full name of responsible person

Hasan Sedaghat

##### Street address

Moalem Blvd

##### City

Boushehr

##### Province

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##### Phone

+98 77 3332 2081

##### Email

s.firoozbakht@bpums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

##### Full name of responsible person

Soroush Ostadzade

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

Sina Dormitory, Hafez Ave., Taleghani Blvd

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Boushehr University of Medical Sciences  
**Full name of responsible person**  
Saeede Firoozbakht  
**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Boushehr University of Medical Sciences  
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s.firoozbakht@bpums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Due to possible use by ourselves for future projects

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available