

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

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2

Recruitment center

Name of recruitment center

Salman Farsi hospital

Full name of responsible person

Soroush Ostadzade

Street address

Sabzabad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Hasan Sedaghat

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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

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

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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