

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of performance of phototherapy inside the incubator with conventional phototherapy method in bilirubin of babies less than 1500gr

Protocol summary

Study aim

Comparing the performance of phototherapy inside the incubator with the conventional method for babies less than 1500 grams

Design

A controlled, randomized, single blinded clinical trial of 50 patients. A coin toss was used for randomization.

Settings and conduct

Preterm babies, weighing less than 1500 grams and age more than 24 hours are included in the study. They will be randomly assigned to intervention and control groups by flipping a coin. This study will be conducted in single blind way so that the data analyzer will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preterm babies, (weigh: less than 1500 grams and age: more than 24 hours) who use breastfeeding or powdered milk feeding, and need phototherapy based on bilirubin level. Exclusion criteria: sick babies (infection, metabolic disease, hemolytic disease), jaundice in the first 24 hours of life, receiving phenobarbital before and after birth, and babies who need blood transfusion.

Intervention groups

In the control group (conventional method), one phototherap is placed above the baby's head and another phototherap is placed next to the baby and outside the incubator for 24 hours. In the phototherapy-inside incubator group, one phototherap is placed above the head of the baby's bed (like the conventional method) and the other device is placed inside the incubator (at the lower end) for 24 hours (unlike the conventional method where the lamp is outside the incubator).

Main outcome variables

Serum total bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191111045400N3**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Mohammad Amin Younesieh Heravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

a.younessi7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of performance of phototherapy inside the incubator with conventional phototherapy method in bilirubin of babies less than 1500gr

Public title

Comparison of performance of phototherapy inside the incubator with conventional phototherapy method

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm babies Weight less than 1500 grams, age more than 24 hours, who were fed with breast milk or formula. Bilirubin levels based on gestational age or birth weight require photo-therapy.

Exclusion criteria:

Sick babies (infection, metabolic disease, hemolytic disease) The occurrence of jaundice in the first 24 hours of life, Receiving phenobarbital before and after delivery. Babies need blood transfusion

Age

To **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Babies were divided into two groups using a random method based on flip the coin method. Group 1: treatment with conventional methods (control group) Group 2: treatment with photo therapy inside the incubator (intervention group)

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer is not aware of the groups under study in analyzing the results.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

Street address

Ethics committee of North Khorasan University of Medical Sciences, Imam Ali Hospital, Daneshgah Ave

City

Bojnurd

Province

North Khorasan

Postal code

74877-94149

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.NKUMS.REC.1401.112

Health conditions studied**1****Description of health condition studied**

Hyperbilirubinemia

ICD-10 code

R17.0

ICD-10 code description

Hyperbilirubinaemia with mention of jaundice, not elsewhere classified

Primary outcomes**1****Description**

Total Bilirubin

Timepoint

Before the intervention, 8 hours after the intervention, 16 hours after the intervention and 24 hours after the intervention.

Method of measurement

Biochemistry auto analyzer and colorimetric method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Phototherapy inside the incubator. One photo-therapy unit is placed above the head of the baby's bed (as usual) and the other unit is placed inside the incubator and at its lower end for 24 hours.

Category

Treatment - Devices

2**Description**

Control group:In the control group (conventional method), one photo-therapy unit is placed above the head of the baby's bed and another photo-therapy unit is placed along the width of the baby's bed for 24 hours.

Category

Treatment - Devices

Type of organization providing the funding

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bint Al-Hadi Bojnurd Hospital

Full name of responsible person

Dr Ghasem Bayani

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No. 38, West Talqani Street, Bint Al Hadi Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

Dr Bahram Bibak

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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

Bojnourd 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****Person responsible for general inquiries****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

Mohamad Amin Younessi

Position

consultant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only laboratory results and research results can be shared

When the data will become available and for how long

beggining of year 2024

To whom data/document is available

just for reaserchers

Under which criteria data/document could be used

no conditions required

From where data/document is obtainable

to the phone number inserted

What processes are involved for a request to access data/document

almost one week

Comments