Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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+98 58 3229 7182

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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
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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

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

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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
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
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consultant
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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