Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of white plastic covering around the phototherapy unit on hyperbilirubinemia in neonates

Protocol summary

Study aim
Determining the Effect of White Plastic Covering Around the Phototherapy Unit on Hyperbilirubinemia in Preterm Neonates

Design
Randomised, open-label, parallel group, superiority trial with blinded outcome assessment. 140 neonates will be enrolled at a single center and randomly assigned (1:1) using computer-generated block randomisation.

Settings and conduct
The trial will be conducted at the neonatal ward of Shahid Beheshti Hospital in Kashan, Iran. Eligible preterm neonates will be enrolled after informed consent and randomly assigned to standard phototherapy or phototherapy with a white plastic cover. Trained nurses will deliver the intervention. The study is open-label, but outcome assessment will be blinded. Data will be recorded using standard checklists.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Gestational age ≥ 35 weeks Indication for phototherapy based on the Bhutani nomogram Informed parental consent Exclusion Criteria: Major congenital anomalies Hemolytic disease (e.g., ABO or Rh incompatibility) Use of phenobarbital or traditional herbal remedies Suspected infection

Intervention groups
In the intervention group, preterm neonates undergoing phototherapy will receive treatment using a white plastic cover placed around the phototherapy unit. The cover is made of glossy white plastic (2 mm thick), enclosing three sides of the device while leaving one side open for observation and care. The control group will receive standard phototherapy without any covering. Both groups will receive the same supportive care.

Main outcome variables
Primary Outcome: Change in total serum bilirubin level before and after phototherapy Secondary Outcomes: Duration of phototherapy (in hours) Rate of bilirubin reduction per hour Incidence of phototherapy-related side effects (e.g., hyperthermia, skin rash, dehydration)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250704066372N1**
Registration date: **2025-07-26, 1404/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-26, 1404/05/04**
Update count: **0**

Registration date
2025-07-26, 1404/05/04

Registrant information
Name
Maryam Kazemiyanfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5510 9999
Email address
maryamkazemi1320@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-24, 1404/05/02
Expected recruitment end date
2026-01-22, 1404/11/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Investigating the effect of white plastic covering around the phototherapy unit on hyperbilirubinemia in neonates

Public title
White Plastic Covering and Its Effect on Newborns' Jaundice

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Neonates with a gestational age ≥ 35 weeks Indication for phototherapy according to the Bhutani nomogram Diagnosis of non-hemolytic neonatal hyperbilirubinemia Parental consent for participation in the study

Exclusion criteria:
Neonates with major congenital anomalies Presence of hemolytic disease (e.g., ABO or Rh incompatibility) Use of drugs affecting bilirubin metabolism, such as phenobarbital Use of herbal remedies (e.g., jujube, shir-khesht, or similar traditional agents) Neonates suspected of having an infection

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization will be used to ensure balanced sample sizes between the two groups. The unit of randomization will be the individual neonate, and no stratification will be applied. The allocation list will be generated using computer-based random number generation with a block size of four, ensuring a 1:1 assignment ratio between the intervention and control groups. The randomization sequence will be prepared by an independent person who will not be involved in patient recruitment. To ensure allocation concealment, sealed, opaque, and sequentially numbered envelopes will be used. Each envelope will contain the assigned group and will only be opened after confirming eligibility and obtaining informed consent from the parents.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This will be an open-label trial due to the visible nature of the intervention (presence or absence of white plastic cover around the phototherapy unit). Neither caregivers nor investigators will be blinded to the group allocation. However, the data analyst will be blinded to the group assignments to reduce detection bias.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the Faculty of Medicine and Dentistry - Kashan University of Medical Sc

Street address
Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City
Kashan

Province
Isfehan

Postal code
8713783976

Approval date
2025-03-02, 1403/12/12

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1403.249

Health conditions studied

1

Description of health condition studied
Neonatal Hyperbilirubinemia

ICD-10 code
P59

ICD-10 code description
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description
Change in total serum bilirubin level before and after phototherapy

Timepoint
Before intervention (at admission), and at 12 hours, 24 hours, and at discharge after the start of phototherapy

Method of measurement
Total serum bilirubin will be measured using standard laboratory blood tests with a validated automated biochemical analyzer. Blood samples will be collected through venipuncture at specified time points.

Secondary outcomes

1

Description
Duration of phototherapy (in hours)
Timepoint
From the start of phototherapy to its discontinuation (measured in hours)
Method of measurement
Duration of phototherapy will be measured by recording the start and end time of phototherapy in each patient's medical chart. The total duration will be calculated in hours.

2

Description
Rate of bilirubin reduction per hour
Timepoint
Calculated between each bilirubin measurement timepoint (e.g., 0–12h, 12–24h)
Method of measurement
The rate of bilirubin reduction will be calculated by subtracting the initial serum bilirubin level from the level measured at subsequent time points, divided by the number of hours between measurements.

3

Description
Side effects (hyperthermia, rash, dehydration)
Timepoint
Every 6 hours during phototherapy
Method of measurement
Side effects will be monitored and recorded every 6 hours during phototherapy by trained nurses. Hyperthermia will be defined as axillary temperature > 37.5°C. Skin rash and signs of dehydration will be clinically assessed and documented.

Intervention groups

1

Description
Intervention group: Preterm neonates will receive standard phototherapy with a white plastic cover placed around the phototherapy unit. The cover is made of glossy white plastic, 2 mm thick, covering three sides of the unit. One side remains open for care and observation.
Category
Treatment - Devices

2

Description
Control group: Preterm neonates will receive standard phototherapy without any plastic cover around the unit. All other care and monitoring will be identical to the intervention group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital
Full name of responsible person
Seyed Amirabbas Sharif
Street address
Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Amir Kabir District, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715973447
Phone
+98 31 5500 9999
Email
beheshtihospital@kaums.ac.ir
Web page address
https://beheshti.kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Vice Chancellor for Research, Kashan University of Medical Sciences, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Amir Kabir District, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5558 9444
Email
hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Seyed Amirabbas Sharif
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Kashan University of Medical Sciences, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Amir Kabir District, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5558 9444
Email
amirsharif.md@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Seyed Amirabbas Sharif
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Kashan University of Medical Sciences, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Amir Kabir District, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5558 9444
Email
amirsharif.md@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Seyed Amirabbas Sharif
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Kashan University of Medical Sciences, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Amir Kabir District, Kashan, Isfahan Province, Iran
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5558 9444
Email
amirsharif.md@gmail.com

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified Participant Dataset – Phototherapy Trial in Preterm Neonates Includes anonymized individual-level data related to primary and secondary outcomes such as serum bilirubin levels, duration of phototherapy, and incidence of side effects. No personal identifiers are included.
When the data will become available and for how long
The data files will be available starting 6 months after publication of the study results and will remain accessible for a period of 3 years.
To whom data/document is available
Deidentified IPD and supporting documents will be shared upon reasonable request with researchers affiliated with academic or healthcare institutions. Access for individuals from non-academic or commercial entities will be considered on a case-by-case basis and subject to

ethical approval.

Under which criteria data/document could be used

Access to deidentified IPD and supporting documents will be granted for secondary analyses that are methodologically sound and ethically approved, such as meta-analyses or validation studies. Requests must be submitted in writing along with a brief study protocol. All requests will be reviewed by the principal investigator and the institutional ethics committee. Decisions will be based on scientific merit, ethical considerations, and alignment with the original consent provided by participants. Data will be shared through secure data transfer platforms.

From where data/document is obtainable

Applicants who wish to access the deidentified IPD or supporting documents should contact the Principal Investigator via email. The preferred method of communication is email. Requests can be sent to: Seyed Amirabbas Sharif amirsharif.md@gmail.com 00989133198472

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

Applicants must submit a written request via email along with a brief description of the intended analysis and a summary protocol. The request will be reviewed by the principal investigator and then forwarded to the institutional ethics committee for approval, if applicable. The entire process, including ethical review and data preparation, may take approximately 4 to 8 weeks. If approved, data will be shared through a secure transfer method, and the applicant must agree to terms of use and confidentiality.

Comments