Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of a White Reflective Cover and Massage as Adjuncts to Standard Phototherapy on Bilirubin Clearance Rate, Phototherapy Duration, and Length of Hospital Stay in Term Neonates with Hyperbilirubinemia: A Randomized Controlled Trial (RCT)

Protocol summary

Study aim

To evaluate the effects of a white reflective cover and infant massage, separately and in combination, as adjuncts to standard phototherapy on bilirubin clearance rate in term neonates with hyperbilirubinemia.

Design

A single-center, four-group, 2 × 2 factorial randomized controlled trial involving 150 term neonates is planned. Participants will be randomly allocated to the four study groups. The study will evaluate the independent effects of each intervention and their interaction.

Settings and conduct

The study will be conducted in the Neonatal Intensive Care Unit of the Maternal and Child Teaching Hospital in Al-Diwaniyah, Al-Qadisiyah Governorate, Iraq. After eligibility screening and written informed consent, participants will be randomized to one of the four groups. Clinical data and serial total serum bilirubin measurements will be collected using a standardized protocol.

Participants/Inclusion and exclusion criteria

Participants will be term neonates born at 37 to 41 completed weeks of gestation with hyperbilirubinemia requiring phototherapy. Written informed consent will be obtained from parents or legal guardians. Neonates with major congenital anomalies, serious clinical conditions interfering with the interventions or outcome assessment, or contraindications to the interventions will be excluded.

Intervention groups

Participants will receive one of four interventions: standard phototherapy alone; standard phototherapy with a white reflective cover; standard phototherapy with infant massage; or standard phototherapy with both a white reflective cover and infant massage.

Main outcome variables

The primary outcome is bilirubin clearance rate, assessed using serial total serum bilirubin measurements. Secondary outcomes are phototherapy duration and length of hospital stay. Outcomes will be compared across the four study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261001071249N1**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date

2026-10-14, 1405/07/22

Registrant information

Name

Hadeer Abdulameer

Name of organization / entity

University of Baghdad, College of Nursing, Iraq

Country

Iraq

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-01-01, 1405/10/11

Expected recruitment end date

2027-03-31, 1406/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a White Reflective Cover and Massage as Adjuncts to Standard Phototherapy on Bilirubin Clearance Rate, Phototherapy Duration, and Length of Hospital Stay in Term Neonates with Hyperbilirubinemia: A Randomized Controlled Trial (RCT)

Public title

Comparing White Reflective Covers and Massage Alongside Phototherapy to Reduce Jaundice in Full-Term Newborn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Term neonates with a gestational age of 37 to 41 completed weeks.2. Neonates diagnosed with hyperbilirubinemia and requiring standard phototherapy according to the treating physician's assessment and applicable clinical guidelines.3. Neonates admitted to the selected study setting during the recruitment period.4. Written informed consent obtained from the parent or legal guardian before enrollment.5. Neonates who meet all study eligibility criteria and can receive the assigned intervention according to the study protocol.

Exclusion criteria:

1. Neonates with major congenital anomalies or serious clinical conditions that may interfere with the study interventions or outcome assessment.2. Neonates requiring urgent treatment or additional therapeutic interventions that would prevent adherence to the study protocol.3. Neonates with contraindications to infant massage or to the use of the white reflective cover, as determined by the approved protocol and clinical assessment.4. Neonates whose clinical circumstances prevent reliable measurement of the study outcomes.

Age

To **40 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Description Eligible term neonates with hyperbilirubinemia will be individually randomized into one of four study groups using a computer-generated random allocation sequence. A block randomization method will be used to help maintain a balanced number of participants across the four groups throughout the recruitment period. The random sequence will be generated using appropriate statistical software before participant enrollment. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared according to the randomization sequence by an individual who is not involved in participant recruitment or outcome assessment. After eligibility confirmation and obtaining written informed consent, the next envelope in sequence will be opened to determine the participant's group assignment. The four groups will receive: (1) standard phototherapy alone; (2) standard phototherapy with a white reflective cover; (3) standard phototherapy with infant massage; or (4) standard phototherapy with both a white reflective cover and infant massage. No stratification will be used unless specified in the approved study protocol.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

This study will employ a four-arm, 2 × 2 factorial randomized controlled trial design to evaluate the independent and combined effects of a white reflective cover and infant massage as adjuncts to standard phototherapy in term neonates with hyperbilirubinemia. Participants will be allocated to one of four groups: standard phototherapy alone, phototherapy with a white reflective cover, phototherapy with infant massage, or phototherapy with both interventions. The study will assess bilirubin clearance rate, phototherapy duration, and length of hospital stay. The factorial design will allow evaluation of the main effects of each intervention and their interaction effect.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Al-Qadisiyah Health Directorate, Research and Development Training Center

Street address

Al-Qadisiyah Health Directorate, Research and Development Training Center, Al-Diwaniyah, Al-Qadisiyah, Iraq

City

Al-Diwaniyah Center

Postal code

58001

Approval date
2026-09-13, 1405/06/22
Ethics committee reference number
N3057105

Health conditions studied

1

Description of health condition studied
Neonatal hyperbilirubinemia
ICD-10 code
Neonatal j
ICD-10 code description
Neonatal jaundice due to excessive hemolysis, unspecified

Primary outcomes

1

Description
Bilirubin clearance rate in term neonates with hyperbilirubinemia receiving phototherapy.
Timepoint
At baseline before the study interventions, and every 12 hours during phototherapy until phototherapy is discontinued, according to the study protocol.
Method of measurement
Bilirubin clearance rate will be calculated from serial total serum bilirubin (TSB) measurements obtained using the hospital laboratory's validated method. The rate will be calculated as the change in TSB concentration divided by the elapsed time between measurements and expressed in mg/dL per hour. Measurements will be performed using consistent procedures across all four study groups.

Secondary outcomes

1

Description
Duration of phototherapy in hours.
Timepoint
From initiation of phototherapy until phototherapy is discontinued according to the treating physician's clinical assessment and applicable guidelines.
Method of measurement
Phototherapy duration will be calculated in hours from the recorded start time to the recorded discontinuation time, using the participant's clinical records.

Intervention groups

1

Description
Intervention group 1: Standard phototherapy with a white reflective cover as an adjunct intervention for term neonates with hyperbilirubinemia.
Category
Treatment - Other

2

Description
Intervention group 2: Standard phototherapy with infant massage as an adjunct intervention for term neonates with hyperbilirubinemia.
Category
Treatment - Other

3

Description
Intervention group 3: Standard phototherapy with both a white reflective cover and infant massage as adjunct interventions for term neonates with hyperbilirubinemia.
Category
Treatment - Other

4

Description
Control group: Standard phototherapy alone for term neonates with hyperbilirubinemia, according to the hospital's routine clinical protocol.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternal and Child Teaching Hospital
Full name of responsible person
Hadeer Abdulameer Shalaan Farhan
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Al-Qadisiyah Health Directorate, Research and Development Training Center, Al-Diwaniyah, Al-Qadisiyah, Iraq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
University of Baghdad

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
University of Baghdad

Full name of responsible person
Hadeer Abdulameer Shalaan Farhan

Position
Principal Investigator

Latest degree
Master

Other areas of specialty/work
Pediatrics

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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
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

Title and more details about the data/document

De-identified individual participant data, the study protocol, statistical analysis plan, informed consent form, clinical study report, and data dictionary related to the randomized controlled trial evaluating a white reflective cover and infant massage as adjuncts to standard phototherapy in term neonates with hyperbilirubinemia.

When the data will become available and for how long

The data and documents planned for sharing will become available after completion of the study and publication of the main results, subject to ethical approval and institutional requirements. They will remain available for a period determined by the responsible institution and applicable regulations.

To whom data/document is available

The data and documents may be made available to qualified researchers for scientifically valid research purposes, subject to applicable ethical and institutional requirements.

Under which criteria data/document could be used

Access will be considered for research proposals with a clear scientific purpose. Data will be shared only in de-identified form, subject to confidentiality safeguards, applicable ethical approvals, and any required data-use agreement.

From where data/document is obtainable

Requests may be submitted to the principal investigator or the corresponding institutional research contact.

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

Researchers should submit a written request describing the research question, proposed analyses, and intended use of the data. Requests will be reviewed by the responsible investigator and, where required, the relevant institutional or ethics committee. Access will be provided only after approval and completion of any required agreements.

Comments

No directly identifying participant information will be shared. Data sharing will be subject to participant confidentiality, ethical approval, and institutional policies.