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Effectiveness of the blanket model of light emitting diode “BLUI blanket” phototherapy on decreasing serum bilirubin levels in physiological jaundice at gestational age ≥ 35 weeks

Submission date
15/05/2023

Recruitment status
No longer recruiting

Registration date
06/06/2023

Overall study status
Completed

Last Edited
06/06/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Neonatal jaundice is a condition where newborns have high levels of bilirubin in their blood, which can be caused by various factors. In Indonesia, the prevalence of jaundice in newborns is relatively high. Current therapies for jaundice often involve conventional phototherapy tools, which have limitations such as separating the mother and baby, hindering breastfeeding, and being less portable.

One alternative is phototherapy blankets, which provide comfort and bonding between the baby and mother, as well as ease of direct breastfeeding. However, existing phototherapy blankets can be expensive. Recent research has focused on developing a simpler and more cost-effective phototherapy blanket using LED arrays. Studies have shown that LED lamps can effectively reduce bilirubin levels compared to conventional fluorescent lamps.

The BLUI Blanket LED phototherapy blanket is an LED-based alternative that has advantages such as lower production costs, easy portability, even radiation distribution, and flexibility in placement. This study aims to develop and evaluate the efficacy and side effects of the BLUI Blanket LED phototherapy blanket compared to conventional phototherapy devices. A randomized controlled trial will be conducted to assess the effectiveness of the new blanket in reducing bilirubin levels in newborns with physiological jaundice.

The goal is to compare the effects of the LED BLUI Blanket phototherapy blanket with traditional phototherapy devices in newborns at 35 weeks gestation who have physiological jaundice. The findings from this study will provide valuable insights into the effectiveness of LED phototherapy blankets and their potential to improve the treatment of neonatal jaundice.

Who can participate?
Infants with a gestational age ≥ 35 weeks and a postnatal age > 24 hours – 14 days with a birth weight ≥ 2000 grams

What does the study involve?
Eligibility and Consent – After receipt of a serum bilirubin level near or above the treatment line when compared with age on an appropriate treatment nomogram, the parents or guardians of the infant will be approached for informed consent by a member of the research team or a neonatal doctor. The investigator will explain the study fully to the patient's parent(s)/guardian (s) using the Patient Information Sheet. Parents will be informed that they may withdraw their child from the study at any time should they wish; and that a decision not to consent to their child's participation in the study or to withdraw their infant from the study once enrolled will not affect their infant's access to the best available care at the RSAB Harapan Kita. Consent forms will be kept securely, and a copy will be provided in the patient's chart. Fully informed written consent will be obtained before enrolment.

Randomisation and Allocation Concealment - Randomisation will occur on receipt of informed consent. A computer-generated random number list will be used, prepared by an investigator with no clinical involvement in the trial. Sequences will be grouped based on the type of phototherapy used - BLUI Blanket and conventional (fluorescent) phototherapy. Once generated, the randomization lists will be sealed in opaque envelopes. Once the patient consents to enter the trial, the investigator(s), doctor on duty, or ANP will open the next sequential opaque envelope in the correct strata and provide the allocated interventions.
Blinding – Blinding of parents or research staff will not be possible due to the nature of the intervention.

Methods
Infants will be randomized after having a serum bilirubin sample that is 'near' the treatment line for their age or less from the treatment line on a treatment nomogram. Both groups will have serum bilirubin samples taken 24 hours until they cross the treatment line and require phototherapy or until they are deemed to be at a safe level from the line and suitable for discharge home. Infants in the control group may also be discharged for repeat samples as an outpatient if deemed appropriate.

Confidentiality
The study team will record data that is routinely collected for each infant in their medical records as part of their routine care. Participation in the study will not necessitate extra investigations or interventions over and above those indicated as part of their routine care. These data will be recorded on dedicated Case Report Forms (CRFs). These CRFs will not contain identifying information of individual infants and will be stored securely. Data that are extracted from these CRFs will be anonymized and entered into databases on password-protected computers.

What are the possible benefits and risks of participating?
An anticipated benefit for the patient's parents is that breast milk can be provided directly to the patient while using the phototherapy blanket.
The benefits for Society include:
- The results of this study can be applied to improve health services for the community, namely in the form of maintaining the bonding between mothers and babies who experience neonatal jaundice, where undergoing phototherapy between mothers and children are not separated.
- Maintain mother-infant contact and do not interfere with direct breastfeeding when the baby receives light therapy.

- Get cheap and affordable phototherapy.
The benefits for General Practitioner Clinicians and Pediatricians include:
- Providing evidence-based information to clinicians that Light Emitting Diode BLUI Blanket phototherapy blankets can be a more practical alternative to reducing bilirubin levels in neonatal jaundice and provide benefits for maintaining mother-infant contact when breastfeeding directly.
- Providing evidence-based information to clinicians that this BLUI Blanket Light Emitting Diode phototherapy blanket has milder side effects.

There is a risk that the phototherapy blanket will not work due to technical problems meaning that phototherapy rays will not perform their function optimally, causing ineffectiveness in lowering bilirubin levels.

Where is the study run from?
Univeritas Indonesia (Indonesia)

When is the study starting and how long is it expected to run for?
February 2020 to May 2024

Who is funding the study?
Education Fund Management Institute, Indonesia Endowment Fund for Education, LPDP (Indonesia)

Who is the main contact?
Tubagus Ferdi Fadilah, tubagus.ferdi@ui.ac.id (Indonesia)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effectiveness of the “BLUI Blanket” light emitting diode phototherapy blanket model against decreased bilirubin in physiological jaundice gestational age ≥ 35 Weeks - a randomised control trial

Study objectives
The proportion of physiologic jaundice neonates whose bilirubin levels decreased by or more than 3 mg/dL from the initial bilirubin level within 24 hours of neonates receiving therapy with LED BLUI blankets will be greater than the proportion of neonates receiving therapy with fluorescent phototherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2023, Research and Community Engagement Ethical Committee, Faculty of Public Health at The University of Indonesia (Gedung Dekanat Fakultas Kesehatan Masyarakat Kampus UI Depok, 16424, Indonesia; +62 21 7864975, 7864976; fkmui@ui.ac.id), ref: Ket- 38/UN2. F10.D11/PPM.00.02/2023

Study design
Single-center two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Neonatal jaundice

Interventions

The trial is a single-center, two-armed, randomized controlled trial. The intervention group will be treated with a BLUI Blanket in the post-natal ward. The control group will have conventional phototherapy (fluorescent overhead lamp). Both groups will be monitored for serum bilirubin levels for 24 hours until they reach a safe level for their age and gestation. A safe level is a serum bilirubin level below the treatment line. Ethical approval has been sought from the Research Ethics Committee in the Faculty of Public Health, Universitas Indonesia.

Sample Recruitment Method

The data collection procedure is carried out through the following steps:

- Pass the ethics test from the FKM UI Ethics Committee
- Pre-recruitment

1. Apply for a research permit from the Director of Harapan Kita Hospital.
2. Research respondents who met the requirements according to the inclusion criteria and exclusion criteria were then taken as research samples with the 4-block model
3. In this study the researchers were assisted by data collectors, namely the head of each inpatient room and nurse in the nursery or perinatology room, who had received instructions about the research objectives and ways to fill out questionnaires and collect data so that they had the same understanding. This activity was carried out for one day in the form of explanations, discussions and questions and answers.

Recruitment

1. Researchers and data collectors meet the parents/guardians of the respondents and explain the purpose and benefits of the research to the parents/guardians of the respondents. After the parent/guardian of the respondent understood the explanation given, the parent/guardian of the respondent was asked for his consent by signing an informed consent as proof.
2. 100 eligible patients were then randomly allocated according to the randomization carried out by the Diklit section without the knowledge of the researchers, blocks were then allocated as patients with interventions and patients with controls.
3. Patients were followed from the start of phototherapy until the phototherapy was discontinued according to medical indications, and data was collected according to the research variables.
4. Blood samples are taken before the intervention (initial), 24 hours, and 48 hours from the start of phototherapy until the bilirubin level reaches the limit allowed to go home by the doctor in charge, namely total serum bilirubin level </=10 mg/dl for late preterm age gestation 35 – 36 6 /7 weeks and </=12 mg/dl for term gestational age >/=37 weeks, and at discharge.

5. Conduct in-depth interviews and surveys with informants, namely doctors, nurses, and parents of patients after the patient has completed phototherapy.

The intervention and timepoints

The intervention group received a Light Emitting Diode BLUI Blanket phototherapy blanket and the control group received fluorescent phototherapy.

The intervention provider

Phototherapy is given by a perinatology nurse who has previously been given training on how to use the tool

Mode of intervention delivery

Phototherapy intervention is given directly to the individual

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III

Drug/device/biological/vaccine name(s)
BLUI Blanket

Primary outcome measure
Bilirubin serum level measured by examination of blood serum at 24 hours after the start of phototherapy

Secondary outcome measures
Side effects measured by physical examination at 24 hours after the start of phototherapy

Overall study start date
01/02/2020

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Infants with gestational age ≥ 35 weeks and birth weight ≥ 2000 grams (p25)
2. Postnatal age > 24 hours – 14 days
3. No history of birth trauma/cephalhematoma/bleeding
4. Total serum bilirubin levels are 10 and less than19 mg/dl (cut-off value for medium risk infants, gestational age 35-36 6/7 weeks and fit), and radar serum bilirubin total 12 less 22 mg/dl (limit value lower risk infants aged ≥ 38 weeks and fit)
5. Asian race
6. No circulatory disturbances, respiratory disorders, and saturation above 90%
7. The patient's parents/guardians agree to participate in the study and sign an informed consent

Participant type(s)
Patient

Age group
Neonate

Lower age limit
2 Days

Upper age limit
14 Days

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Genetic, metabolic disorders, hemolytic anemia (examination of GDS levels, blood group, and rhesus, peripheral blood picture)
2. Infection (clinical fever or hypothermia and increased leukocyte laboratory tests)
3. The direct bilirubin level exceeds 2 mg/dl or 20% of the total serum bilirubin level

Date of first enrolment
01/05/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
Indonesia

Study participating centre
Harapan Kita Mother and child Hospital
Jl. Letjend. S. Parman Kav. 87 Slipi
Jakarta
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11420

Sponsor information

Organisation
Lembaga Pengelola Dana Pendidikan

Sponsor details
Indonesia Endowment Fund for Education
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10330
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Sponsor type
Government

Website
https://lpdp.kemenkeu.go.id/en/informasi/hubungi-kami/

ROR
https://ror.org/05p2xef58

Funder(s)

Funder type
Government

Funder Name
Lembaga Pengelola Dana Pendidikan

Alternative Name(s)
Education Fund Management Institute, Indonesia Endowment Fund for Education, LPDP

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The datasets generated or analyzed during the current study will be published as a supplement to the result publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			31/05/2023	No	No