ISRCTN88608924 https://doi.org/10.1186/ISRCTN88608924

Light treatment (phototherapy) from multiple directions is significantly better than unidirectional light treatment in this pilot study of term breast-fed infants with jaundice

Submission date
18/01/2026

Recruitment status
No longer recruiting

Registration date
29/01/2026

Overall study status
Completed

Last Edited
29/01/2026

Condition category
Neonatal Diseases

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

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Susanna Magee

ORCID ID
https://orcid.org/0009-0001-3610-4763

Contact details
Landmark Medical Center
206 Cass Ave
Woonsocket
United States of America
02895
+1 4017671576
susannamagee@gmail.com

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Susanna Magee

Contact details
Landmark Medical Center
206 Cass Ave
Woonsocket
United States of America
02895
+1 4017671576
smagee@primehealthcare.org

Additional identifiers

Study information

Scientific Title
Multidirectional phototherapy versus phototherapy from below for severe neonatal jaundice: a pilot study in Home phototherapy

Study objectives
This study was a comparison of the Medela Bilibed versus the Little Sparrows bili-hut for the treatment of neonatal jaundice in the home setting

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/06/2022, St Michael’s Institutional Review Board (111 Central Ave, Newark, 07102, United States of America; +1 973 877 2663; Jfallon@primehealthcare.org), ref: 21-Jun2022#18 /21

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Severe neonatal jaundice

Interventions
Study patients were comprised of infants referred to a single licensed/accredited home health agency in Rhode Island by their outpatient pediatrician for home phototherapy for neonatal jaundice. All infants were ≥37 weeks gestational age and ≥ 2500 grams at the beginning of the treatment. All infants were discharged from the hospital with no evidence of clinical hyperbilirubinemia; the infants in our study were diagnosed with jaundice in the office of their pediatrician at the first office visit post-hospital discharge. In addition, only exclusively breastfeeding dyads were enrolled. Following referral to the home health agency for phototherapy treatment by the outpatient pediatrician, the study was explained to the parents by the nurses employed at the home health agency. After written informed consent, enrolled infants were randomized at a 1:1 ratio to either high-intensity treatment from below or multidirectional phototherapy. Randomization was based on a computer-generated sequence at the home health-care agency, with device assignment provided to the treating nurse. A nurse visited the home daily, clinically assessed the infant and obtained a blood sample for serum bilirubin measurement. This blood sample was then delivered to a CLIA-certified laboratory for processing. The decision to end phototherapy was made by the child's pediatrician after receiving a report of the bilirubin value from the visiting nurse. Families were not told which device they were assigned. Because the devices are visually different and have different operating instructions, the clinical care team was not blinded. However, the laboratory personnel processing the serum bilirubin levels were blinded to the type of treatment the infant was receiving (multi vs. unidirectional). Additionally, the outpatient physician responsible for each infant was blinded to the type of treatment the infant was receiving in the home (multi vs. unidirectional therapy). Demographic variables collected include gestational age at birth, weight, and postnatal age in hours at the onset of treatment. Clinical data collected include serial serum bilirubin concentrations and treatment duration. The diagnostic bilirubin drawn by the outpatient pediatrician who detected jaundice at the office-based visit was used as the starting value. After that blood draw, families returned home. If the bilirubin level was elevated and the infant was a candidate for treatment at home with the visiting nurse, they were offered this option. Once they called the home health agency, the families were given the option to participate in the study. For those who consented and were randomized to multi- or unidirectional treatment, bilirubin was then measured daily until treatment was complete. A bilirubin was also collected 8-24 hours following cessation of treatment if desired and ordered by the pediatrician. Duration of phototherapy was anywhere from 10-50 hours total and was measured using built-in timers on both devices. Parents were instructed to turn the light off when the baby was removed for feeding and care. All serum bilirubin levels were reported to the visiting nurse, who in turn reported them directly to the pediatrician. The pediatrician would then instruct the visiting nurse to continue therapy or discontinue phototherapy. The trial data were collected and maintained in the same manner for all infants who received phototherapy during the study period. The primary outcome was treatment time in hours and secondary outcomes were reduction in serum bilirubin level and the estimated serum bilirubin reduction rate. Variables are expressed as mean +/-standard deviation. Differences in the means for treatment times in the two groups are determined by an unpaired t-test. Serum bilirubin was collected by the visiting nurse in the home setting, transported to the laboratory by said nurse and measured with standard instruments in CLIA-certified hospital and office laboratories. The lab personnel were not informed of the treatment arm for the patient sample they were processing. The rate of bilirubin reduction was estimated by calculating the change in bilirubin

/treatment time for each infant, with values averaged for the mean. No adjustment was made for elapsed time between blood collection and initiation of phototherapy or between cessation of phototherapy and blood collection.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Little Sparrows bili-hut, Medela Bilibed

Primary outcome(s)
1. Serum bilirubin level measured using blood test at prior to phototherapy after 8 to 12 hours of therapy and 8 to 12 hours later, approximately

Key secondary outcome(s))

Completion date
27/06/2023

Eligibility

Key inclusion criteria
1. Hyper bilirubinemia
2. Breast-fed
3. Term
4. Otherwise well

Healthy volunteers allowed
Yes

Age group
Neonate

Lower age limit
2 days

Upper age limit
10 days

Sex
All

Total final enrolment
17

Key exclusion criteria

1. Hospitalized
2. Premature
3. Those are received phototherapy in the hospital prior to discharge
4. Non-breast-fed infants

Date of first enrolment
20/03/2022

Date of final enrolment
25/06/2023

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
Saint Michael's Medical Center

Funder(s)

Funder type

Funder Name
Landmark Medical Center

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available