ISRCTN12080436 https://doi.org/10.1186/ISRCTN12080436

Massage to reduce bilirubin in newborns

Submission date
23/03/2025

Recruitment status
No longer recruiting

Registration date
25/03/2025

Overall study status
Completed

Last Edited
25/03/2025

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
Background and study aims
Yellowing of the skin and mucous membranes (jaundice) is a very common problem and can cause brain damage in babies. It has been reported that Vimala massage can help reduce this.

Who can participate?
All newborns aged 34 to 36.6 SDG according to the Ballard Scale hospitalized for yellowing of the skin and receiving light treatment to reduce the yellow coloration.

What does the study involve?
Participants are randomly allocated to the Vimala massage group (applied by the mothers twice a day for 3 consecutive days) or the control group (standard care). Serum bilirubin, number of stools, phototherapy requirement, and hospital stay were compared between the groups.

What are the potential benefits and risks of participating?
The possible benefits are the Vimala massage will reduce the time of light treatment and therefore the number of days of hospitalization.

Where is the study being conducted?
IMSS UMAE Hospital No. 48 in León (Mexico)

When does the study begin and how long is it expected to last?
June 2021 to February 2023

Who is funding the study?
Mexican Social Security Institute (Mexico)

Who is the primary contact?
Dr Alma Patricia González, alma.gonzalezx@imss.gob.mx

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Alma Patricia Gonzalez

ORCID ID
https://orcid.org/0000-0002-3401-7519

Contact details
Av. Mexico e Insurgentes
Leon
Mexico
37296
+52 (0)4771329126
alma.gonzalezx@imss.gob.mx

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R-2021-1002-04

Study information

Scientific Title
Effect of Vimala massage on serum bilirubin levels in late preterm newborns with neonatal jaundice: a randomized clinical trial

Acronym
MAVIHY

Study objectives
Vimala massage in conjunction with phototherapy reduces bilirubin levels in late premature newborns.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/07/2021, Ethics Committee for Health Research 1028 (Av. Mexico e Insurgentes S /N , Col. Los Paraísos, León Guanajuato, 37328, Mexico; +52 (0)4771329126; 10028hgp48@gmail. com), ref: R-2021-1002-04

Study design
Single-blind randomized clinical trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperbilirubinemia in late premature newborns

Interventions
Randomization was done by random numbers in the Vassar Stata program. Late preterm infants 34 to 36.6 weeks of gestation with hyperbilirubinemia and treatment with phototherapy were randomized to the Vimala massage group (applied by the mothers twice a day for 3 consecutive days) or the control group (standard care).

Both groups received phototherapy and standard newborn care measures, with the study group additionally receiving Vimala massage.
The mothers of the newborn were trained prior to the first day of the study in the Vimala massage technique by one of the experienced researchers and it was applied following the technique and methodology of Vimala McClure at AIM (International Association of Infant Massage). A mannequin was used where the researcher showed the mothers through simulation how to perform the massage and it was reinforced with the explanation with drawings of the massage step by step. A checklist was made at the end of the demonstration to verify learning and when 80% approval of the list was reached, it was taken as learned.

The mothers gave the massage with moderate pressure for a duration of 15 to 20 min according to the acceptance of the newborn and twice a day during visiting hours (at 12:00 and 18:00).

The massage was performed in two phases. During the first phase, the patient was placed in a supine position and the massage was applied: following this order:
1. Face: gently massage the forehead with the thumbs outward, from the nose to the cheeks; they ran their thumbs from the upper lip to the cheeks, then under the ears with the index and middle fingers from the ears to the chin
2. Arms and hands: gently massage the armpit with circular movements; they slid their hands from the shoulder to the wrists; they used twisting motions in the opposite direction, gently rotating each finger for a circular massage on the back of the hands. In addition, slide your hands from wrist to shoulder with twisting motions on arms and forearms
3. Chest: both hands slid starting from the midline to the sides, from the sides to the midline, then from the midline to the right shoulder and back to the midline, then from the midline to the left shoulder and back to the midline. Extend both arms and cross over the chest
4. Abdomen: (“I love you”), the massage was performed from the location of the upper left abdomen to the right below the ribs downwards, and then it starts from the upper right abdomen exactly below the ribs to its opposite point, then downwards, perpendicular to the abdomen and alternating both hands like a "cogwheel"
5. Legs and feet: hands slid from thigh to ankle, twisting in opposite directions over thigh, leg, and foot; twist each toe; dorsiflexion of the sole of the foot and dorsum of the foot; circular movements in ankles; slide hands from ankle to thigh in upward motions.
Second stage: the child was placed face down. Both hands slid from the back of the neck to the hips from top to bottom. They slid their hands from side to side in opposite directions; with the index and middle fingers they drew circles from top to bottom following the spine. They slid their fingertips from her head to her hips, up and down as if she were combing her hair.

Intervention Type
Behavioural

Primary outcome(s)
Serum bilirubin was measured on a 0.5 ml blood sample drawn from the dorsal plexus of the hand preferably, at 6:00 a.m. during the 3 days of the study. Bilirubin was measured with non-enzymatic methods using the chemical reaction that uses nitrous oxide to form a colour complex. Total serum bilirubin was determined by adding caffeine benzoate and diazo reagent in the same way as direct bilirubin. Finally, indirect bilirubin was calculated by subtracting total bilirubin minus direct bilirubin.at baseline and on the third day of treatment.

Key secondary outcome(s))
1. The number of stools quantified daily by the nursing staff during the 3 days of the study: number of evacuations obtained by the nurse on each shift and recorded on the corresponding vital signs and fluid balance control sheet
2. The number of days of need for phototherapy, considered according to the NICE Guidelines for hyperbilirubinemia
3. The length of hospital stay, including the number of days of hospitalization

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Preterm newborns of 34 to 36.6 weeks of gestation were included according to the Ballard scale
2. On phototherapy for indirect hyperbilirubinemia according to the NICE jaundice guidelines
3. Mother willing to apply the Vimala massage

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
1 days

Upper age limit
6 days

Sex
All

Total final enrolment
86

Key exclusion criteria
Neonates with a diagnosis of isoimmunization, inborn errors of metabolism, dehydration or hemodynamic instability or with a mother who withdrew from participating

Date of first enrolment
20/07/2021

Date of final enrolment
20/02/2023

Locations

Countries of recruitment
Mexico

Study participating centre
Unidad Médica de Alta Esecialidaad HGP No 48 IMSS
Av. Mexico e Insurgentes s/N, col. Los paraísos
León Guanajuato
Mexico
37328

Sponsor information

Organisation
Mexican Social Security Institute

ROR
https://ror.org/03xddgg98

Funder(s)

Funder type
Government

Funder Name
Instituto Mexicano del Seguro Social

Alternative Name(s)
Mexican Social Security Institute, IMSS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dra A. Patricia González (alma.gonzalezx@imss.gob.mx)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes