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Emollient therapy for hospitalised very low birth weight newborns: improving survival and health

Submission date
31/12/2025

Recruitment status
Recruiting

Registration date
06/01/2026

Overall study status
Ongoing

Last Edited
05/01/2026

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

Background and study aims
Neonatal deaths account for nearly half of under-five child deaths globally, with complications of preterm birth being the leading cause. Very low birth weight (VLBW) infants are particularly vulnerable due to their immature skin barrier and poses risks such as water loss, infections, and poor growth. Secondary analysis of our data from prior research in Uttar Pradesh indicates that about 1% of infants are born VLBW but these infants account for 13% of neonatal deaths. Emollient therapy that uses natural oils with beneficial fatty acid profiles, like safflower seed oil (SAO) and sunflower seed oil (SSO), has shown promise in enhancing skin barrier function, reducing infections and improving growth. While limited evidence exists on its impact on mortality (death rates), subgroup analyses from our previous study suggest significant reductions among VLBW infants receiving emollient therapy.
Addressing this gap, this study will evaluate the effect of cold-pressed SAO (chosen for its high linoleic acid content and proven anti-inflammatory and antimicrobial properties) on pre-discharge mortality in VLBW infants, contributing to global efforts to reduce neonatal mortality. We believe that available evidence sufficiently constitutes proof of principle, especially considering the well-understood mechanistic basis. However, a well-designed RCT is required to validate these findings.
The proposed multi-center study is sufficiently powered to assess the impact of emollient therapy with SAO (a skin-barrier-enhancing oil) on the survival and health outcomes of VLBW infants in SNCUs, thus addressing a critical research gap.

Who can participate?
The study will include very low birth weight infants who:
1. Weigh ≥1000 g to <1500 g upon admission to the SNCUs/ NICUs of the study facility
2. Are admitted to the SNCU or NICU of the study hospital within 24 hours of birth
3. Have mothers/ families are willing to provide consent for participation in the study

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The study involves providing infants in the intervention group with gentle application of safflower seed oil

(SAO) three times daily along with routine hospital care. The oil will be applied at a dose of approximately 3 g/kg of body weight to the baby's skin by a trained study nurse, following hand hygiene and a standardised application procedure. Infants in the control group will receive routine hospital care but will not receive oil application.

What are the possible benefits and risks of participating?
Very low birthweight (VLBW) infants who require admission in SNCU/NICU will be enrolled in this study. Since they have premature and underdeveloped skin barriers, it makes them all the more prone to infections. Emollient therapy, specifically with safflower seed oil (SAO) is known to enhance the skin barrier development and function, thereby reducing the risk of infection. Additionally, the intervention has demonstrated positive effects on infant growth, contributing to their overall physiological well-being of VLBW infants. However, participants in the control arm may not benefit from the study.
There are no major risks expected from participating in this study. There is already ample evidence supporting that emollient therapy with barrier-enhancing oils itself doesn't pose any major risks, rather it reduces the risk of infections and has shown to improve growth in VLBW infants. Participation will not involve any extra cost. Minor risks may include severe adverse occurrences such as skin irritation, allergic reactions, minor skin rash or skin infections, severe generalised hypersensitivity reaction, phototherapy burn and hyperthermia. While the likelihood of these occurrences is very low, we will actively monitor these conditions and they will be notified to the DSMB within 24 hours of occurrence.
Both groups will continue to receive all necessary routine medical care. If any medical problem arises, appropriate treatment will be provided immediately as per hospital protocol. All information collected during the study will be kept strictly confidential.

Where is the study run from?
The study will be conducted in Sick Newborn Care Units (SNCUs) and Neonatal Intensive Care Units (NICUs) across multiple sites in India

When is the study starting and how long is it expected to run for?
September 2025 to April 2027

Who is funding the study?
Indian Council of Medical Research (ICMR) (India)

Who is the main contact?
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Additional identifiers

Clinical Trials Registry - India (CTRI)
CTRI/2024/01/062058

ICMR Proposal ID
IIRPIG-2023-0000819

Study information

Scientific Title
Impact of emollient therapy for hospitalised very low birth weight newborns on their survival and health outcomes - a randomised controlled trial

Acronym
EmollientVLBW

Study objectives
Primary objective:
1. To assess the impact of emolliation with SAO (thrice daily application of 3 g/ kg weight) vs no emolliation on pre-discharge mortality of VLBW infants.

Secondary objectives:
1. To compare clinical outcomes - neonatal mortality rate, incidence of sepsis, neonatal skin

condition, and length of hospital stay in intervention vs. control groups.
2. To compare growth outcomes - mean weight gain velocity, increase in head circumference (mm/ week), and mid-upper arm circumference (MUAC), in intervention vs control groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 12/12/2023, Institutional Ethics Committee Community Empowerment Lab, Lucknow (5/9, Community Empowerment Lab, Vineet Khand-5, Gomtinagar, Lucknow, 226010, India; +91 (0)8810725123; irb@cel.org.in), ref: CEL/RES/202412/002

2. approved 03/12/2024, Ethics Committee GSVM Medical College Kanpur (Room No. 125, First Floor, GSVM Medical College, Kanpur, 208027, India; +91 (0)9415039582; ecgsvm@gmail.com), ref: EC/BMHR/2024/238

3. approved 13/02/2025, IEC Sarojini Naidu Medical College Agra (Room no. 11, 1st floor, Transfusion Medicine Department, SNMC, Agra, 282002, India; +91 (0)9756966669; ecsnmc20@gmail.com), ref: SNMC/IEC/2025/15

4. approved 17/05/2025, BHU IMS IEC (IEC BHU IMS, 3rd Floor, Aurobindo Colony, Bhelupur, Varanasi, 221005, India; +91 (0)8968577926; libraanu.99@gmail.com), ref: IMS/IEC/2025/8066

5. approved 23/04/2025, IEC Osmania Medical College (Koti, Hyderabad, Hyderabad, 500095, India; +91 (0)40 24651936; ecomchyd@gmail.com), ref: IEC/OMC/M.NO.87(CT)-123

6. approved 06/12/2025, IEC JSS Medical College (Sri Shivarathreeshwara Nagara, Mysuru, Karnataka, 570015, India; +91 (0)8212548345; jssmc@jssuni.edu.in), ref: JSSMC/IEC/24102025 /09 NCT/2025-26

7. submitted 17/12/2025, Institutional Ethics Committee KGMU Lucknow (Office of Ethics Committee, KGMU, Lucknow, 226003, India; +91 (0)9235237435; ethics@kgmcindia.edu), ref: 3864/ped/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Prevention, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Very low birth weight infants

Interventions
This study is an open-label, individually randomised controlled trial. After written informed consent is obtained from the parents or caregivers for enrolment, eligible infants will be randomly allocated to either the intervention or control group.

A study biostatistician has generated a computer-based randomisation sequence using random permuted blocks of variable sizes (2, 4 and 6), separately for each participating facility. The randomisation sequence for each site will be securely stored within the REDCap database.

At the time of enrolment, once consent is confirmed, the REDCap system will automatically assign the infant to the next available allocation in the sequence. The assigned study group will be recorded in the database, without making it visible in the case report forms. As this is an open-label trial, the screening, enrolment, and intervention teams will be aware of group allocation.

Infants assigned to the intervention group will be provided thrice-daily applications of SAO with a dose of about 3 g/kg body weight of SAO applied gently to the baby's skin post-handwashing using a standardised procedure by the study nurse. The study nurse will be responsible for maintaining the quality of the application along with the quantity of SAO used, ensuring consistency and compliance with the protocol. Each session of emolliation will be logged with basic details including the time, provider, duration of emolliation, quantity of oil applied, etc. Post-discharge, the family will be supplied the study oil to enable them to continue the therapy until the age of 28 days.

Infants assigned to the control group will not receive emollient therapy. All infants in both the intervention and control groups will continue to receive routine clinical care as per the existing standard of care protocols followed in the SNCU/NICU of the study facility.

Intervention Type
Other

Primary outcome(s)
1. Pre-discharge mortality rate measured using the percentage of enrolled very low birth weight (VLBW) infants who die before being discharged from the hospital at continuously during the hospital stay till discharge or till 28 days of stay, whichever is earlier

Key secondary outcome(s))
1. Neonatal mortality rate: the percentage of deaths among enrolled very low birth weight (VLBW) infants, measured using clinical records (pre-discharge mortality) and caregiver reports (post-discharge mortality for infants discharged earlier than 28 days) at within the first 28 days of life

2. Incidence of suspected sepsis: the occurrence of systemic infection in enrolled very low birth weight (VLBW) infants, measured using a positive sepsis screen at collected continuously during the hospital stay till discharge or till 28 days of stay, whichever is earlier

3. Skin condition measured using visually based on the amount and degree of skin dryness, scaling, fissuring, erythema, crusting, and oozing, using 0-10 skin score scale, at the time of enrolment, with subsequent measures at ages 3, 7, 14, and 28 days or at the time of discharge, whichever is earlier by the attending physician

4. Duration of hospital stay: the total number of days an enrolled very low birth weight (VLBW) infant remains admitted to the hospital from the time of birth until discharge, measured using hospital records at discharge

5. Weight gain velocity measured using digital infant weighing scale (Seca 334 or equivalent, with precision ± 5 g) at until discharge or day 28, whichever is earlier

6. Head circumference growth velocity (mm/week) measured using Seca 212 or equivalent, with precision ± 1 mm (1/16 inch) at admission, day 14, and discharge or day 28, whichever is earlier

7. Mid-upper arm circumference (MUAC) measured using circumference of the upper arm at the midpoint between the shoulder and elbow at admission, day 14, and discharge or day 28, whichever is earlier

Completion date
15/04/2027

Eligibility

Key inclusion criteria
All hospitalised newborns in the study facility who:
1. Weigh ≥1000 grams and <1500 grams upon admission (as per study scale)
2. Are <24 hours old at the time of admission
3. Are singletons, or in case of multiple births, the oldest infant meeting all eligibility criteria

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
27 days

Sex
All

Total final enrolment
2300

Key exclusion criteria

1. Infants with generalised skin disease (these are likely to have a defect in epidermal barrier function)
2. Critically ill infants requiring Level 3 or above newborn care, including:
2.1. Requiring invasive mechanical ventilation
2.2. In shock
2.3. Severe neurological signs - Repeated seizures unresponsive to first-line antiepileptic treatment, or other signs of severe encephalopathy
3. Life-threatening congenital anomaly or a major surgical condition requiring intervention, e.g. Congenital syphilis, hydrops fetalis, or any other condition that either interferes with the provision of the intervention (e.g., severe eczema, blistering skin disorders, open wounds) or where the intervention may interfere with the provision of care (as assessed by the treating paediatrician at the time of enrolment)

Date of first enrolment
25/09/2025

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
India

Sponsor information

Organisation
Indian Council of Medical Research

ROR
https://ror.org/0492wrx28

Funder(s)

Funder type

Funder Name
Indian Council of Medical Research

Alternative Name(s)
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, ..., ICMR, ICMRDELHI, ...

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available