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Can an intervention involving improvements in community-based newborn massage practice with promotion of cold-pressed sunflower oil as preferred emollient improve newborn survival in rural North India?

Submission date	**Recruitment status**	[X] Prospectively registered
08/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2022	Neonatal Diseases	

Plain English summary of protocol

Background and study aims

Serious infections and complications due to premature birth together are responsible for almost 60% of newborn deaths worldwide. The human skin is a very important organ that serves as a barrier to infection. The skin barrier of the newborn, and especially those babies born prematurely, is thin and is functionally not fully mature. It is also often covered with a thick, waxy substance called vernix; this would have protected the babies skin from amniotic fluid while in the womb. Some communities in the north Indian belt, such as Nepal and Bangladesh perform several practices on newborns that can affect the skin barrier and, therefore, increase the risk of infection. These include the forceful removal of the vernix, often with coarse substances that can damage the skin, and regular massage of babies with flour or mustard seed paste (known to be abrasive to newborn skin).The babies are then massaged with mustard oil, known to delay skin recovery. The aim of this study is to promote the use of cold-pressed sunflower seed oil for massaging babies, along with improved and more hygienic massage practices. These are known to lead to quicker skin recovery and fewer cases of infection, and therefore death, among hospitalised newborn babies in areas where there are few resources. We are investigating whether these practices lead to few newborn babies death in the community as well.

Who can participate?

All newborns identified within the study area until 7 days after their delivery are considered eligible for the trial.

What does the study involve?

Mothers and pregnant women who agree to participate are randomly allocated into one of two groups. For the intervention group, women who traditionally massage newborns during the first 10 to 12 days of life (called nauns) are trained in the improved and hygienic massage technique.

Cold pressed sunflower oil is given to all mothers in the group with instructions on how to use it. The nauns also train mothers and families in the improved massage technique. Mothers in group 2 (the control group) continue following traditional massage practices. The study tracks vital events (pregnancies, births, newborn deaths) in the entire study area through a prospective follow-up of all mothers until 28 days after delivery. Newborn deaths in the intervention and control groups are compared, along with changes in practices and other indicators to assess the effect the new treatment has on the community.

What are the possible benefits and risks of participating?
The sunflower oil and massage techniques used by those in the intervention group is not expected to cause harm to newborn babies and may result in fewer newborn infections and deaths. Sunflower oil is a natural oil that is safe for massage and has been used previously in hospital based studies. Mothers and caregivers are trained by nauns (community masseuses) in the practice of improved and hygienic massage that will mitigate risk to the newborns skin barrier function. There is no additional risk to infants in the control group who will continue to receive traditional newborn massage as practiced by families.

Where is the study run from?
Community Empowerment Lab (India)

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
World Health Organization, Geneva, through a grant from the Bill & Melinda Gates Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO Reference No.: RPC667 The Universal Trial Number (UTN): U1111-1158-4665

Study information

Scientific Title
Impact of topical application of cold-pressed sunflower seed oil with improved massage practices on neonatal mortality: a cluster randomized controlled trial in rural North India

Study objectives
Promotion of cold-pressed sunflower seed oil (SSO) as the emollient of choice coupled with improved newborn massage practices in comparison with standard massage practices in the community will lead to:
1. At least 20% reduction in neonatal mortality rate after 24 hours of birth. (Based on the current mechanistic understanding of how this intervention works, we do not have reasons to believe that there would be any impact on mortality during the first 24 hours)
2. At least 15% reduction in neonatal mortality rate. (As we expect the intervention to impact mortality post 24 hours, therefore when we include deaths in the first day, we would expect the overall impact on NMR to be slightly less at 15%.)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1.Community Empowerment Lab Institutional Ethics Committee (CEL IEC), 07/06/2014, ref. CELIEC/2014001
2. World Health Organization Research Ethics Review Committee (WHO ERC), 12/06/2014, ref RPC667

Study design
Single-center cluster randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
https://drive.google.com/file/d/0Byis_3EIKNsUb1pOSVNZUGdONU0/edit?usp=sharinghttps://drive.google.com/file/d/0Byis_3EIKNsUbXZheWpBczV0NU0/edit?usp=sharing

Health condition(s) or problem(s) studied
Neonatal mortality rate

Interventions
The technical intervention essentially consists of:
1. The product, i.e. cold-pressed sunflower seed oil
2. Directions for newborn massage. The directions for newborn massage further consist of the following aspects:
2.1. Dosage of SSO, comprising of frequency of use, quantity per use, and duration of use.
2.1.1. Dose: 10g per application, applied 3x daily
2.1.2. Duration: 0-27 days of life
2.2. Improvements in overall massage practice:
2.2.1. Encourage hand washing prior to massage
2.2.2. Encourage gently massaging the vernix into the newborn skin, rather than forcefully removing it
2.2.3. Promote gentle massage of newborns
2.2.4. Delay use of mustard oil and skin-scrubbing substances such as bukwa (coarse-grained paste made of mustard/wheat seeds along with additives) past the newborn period
2.2.5. Ensure that the newborn is kept warm during and after massage

Pregnant women who intend to deliver in the intervention area and consent to participate in the trial would be oriented to the intervention and provided an initial supply of oil at 24-27 weeks of gestation, in order to ensure early application on preterm newborns. After birth, oil supply will be replenished on a regular basis by logistics officers. All traditional massage providers (called nauns) providing services in the intervention area would be trained in improved massage practice, and will be expected to train mothers and care providers in the recommended practice.

No such intervention will be introduced in the control group, which will continue following the same traditional massage practices, including the type of oil used.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. NMR post-24 hours of birth or the number of neonatal deaths that occur after 24 hours of birth, per 1000 live births.
2. Neonatal mortality rate (NMR) or the number of neonatal deaths per 1000 live births.

Secondary outcome measures
1.Infections and hospitalization: Signs and symptoms of infection during the newborn period, along with episodes of hospitalization would be recorded through parent recall. These will include local infections such as pyoderma and umbilical cord infection.
2. Growth: Weight of the baby as close as possible to birth (Day 0) and on Day 28, would be

measured through standardized infant weighing scales and procedures.
3. Mechanisms: Mechanistic studies will be conducted on a random sub-sample (5%) of babies from both arms on days 1, 3 and 7. These include studies to understand the biological effects of the intervention on newborn skin. The aim of studying mechanisms is also to attempt to find potential markers that may be used to test the protective effect of oils alone. The parameters that would be included are:
3.1. Videography of massage to document variations in practice
3.2. Skin barrier function: Barrier property of Stratum Corneum (assessed as trans-epidermal water loss or TEWL)
3.3. Neonatal skin scoring using an appropriate scale (for example, the scale used by Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), or the Neonatal Skin Risk Assessment Scale for predicting skin breakdown in newborns).
3.4. We will also explore the use of high resolution imaging techniques to assess skin condition.
4. Dose response: Any relationship between the exclusive application of provided oil, and the duration and frequency of massage practiced by the family, and the morbidity and mortality outcomes will be assessed.
5. Intervention coverage: We will measure the percentage of mothers/ families that were reached through the intervention delivery strategy, received the intervention through an accredited Naun and received sufficient oil supplies.
6. Changes in practices: We expect the neonatal mortality in the intervention arm to be reduced through changes in practices related to newborn skin care, massage and oil use. Therefore changes in these practices is an important process outcome of the study. We will also measure other key newborn care practices including care-seeking, which are not hypothesized to be different between the intervention and control arms.
7. Adherence to Intervention: Information on continued oil use and adherence to massage technique would be obtained from families (mothers). This would also be applicable to a sub sample (5%) of the population.

Overall study start date
01/01/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
All newborns (or neonatal deaths) identified in the study area till 7 days of delivery irrespective of place of delivery will be considered as eligible for analysis of trial outcomes. The inclusion criteria would be met in the community, in the following conditions:
1. Mother stays through the antenatal period and delivers in the study village
2. Mother delivers outside the study village (e.g., maternal home or health facility) but returns to the study village within the first 7 days of delivery
3. In case of maternal deaths, newborns identified in the study villages within 7 days of delivery
Thus, all women/babies who are found to be residing in a particular cluster at the time of first identification during the first 7 days of delivery will be analyzed as part of the same cluster, irrespective of migration or place of delivery, as per principles of intention to treat.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
41,072 newborns from 276 clusters

Total final enrolment
26587

Key exclusion criteria
None. All babies fulfilling the inclusion criteria will be included in the study.

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
India

Study participating centre
Community Empowerment Lab
Lucknow
India
226001

Sponsor information

Organisation
World Health Organization (Switzerland)

Sponsor details
Department of Maternal, Newborn, Child and Adolescent Health
World Health Organization
Avenue Appia 20
1211
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1211

Sponsor type
Government

Website
http://www.who.int/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Other

Funder Name
World Health Organization (WHO) Geneva (Switzerland)

Funder Name
Bill & Melinda Gates Foundation (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/09/2021	29/09/2021	Yes	No
Results article		04/01/2021	05/01/2022	Yes	No