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A pilot study to understand the best way of applying antiseptic, with or without sunflower oil, to low birth weight newborn babies who are in hospital

Submission date
07/04/2020

Registration date
18/06/2020

Last Edited
01/03/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Neonatal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This is a pilot study to assess the best way of applying antiseptic to low birth weight newborn babies who are in hospital. The antiseptic aims to reduce the amount of potentially harmful bacteria on the skin of newborn babies. This might be useful for preventing infections which are picked up in hospital.

This study aims to find out the best concentration of antiseptic to use, as well as how often it should be put on the babies, and whether or not it should be combined with a skin softener. In this pilot study, the researchers will see the amount of bacteria babies have on their skin, and look carefully at whether, and how often, skin reactions occur.

The antiseptic the researchers will test in this study is called chlorhexidine. Chlorhexidine has been widely used across the world for many decades to reduce the risk of babies dying from infection. For example, it is put on the umbilical cord of newborn babies at home in areas with high rates of deaths from infections. However, the researchers don't know whether applying chlorhexidine to the body could reduce the risk of infection and death in newborn babies who are in hospital and have a high risk of infection because of other problems, like being premature or low birth weight.

In addition, skin softeners (also called emollients), which are often in the form of oils such as sunflower oil, have been shown in some, but not all, studies to reduce infections. The researchers do not know whether combining emollients and an antiseptic may work even better, so the researchers will also look at this in this pilot study.

Who can participate?
Babies aged 1-6 days.

What does the study involve?
The study will be conducted in two hospitals, one in Bangladesh, and the other in South Africa. Chlorhexidine will be put on the skin of the body of some of the babies, starting at 1-6 days of age and either on working days or on alternate working days of the week.

Different babies will get different concentrations of chlorhexidine. Some babies will also get skin softeners applied. And some babies will just be followed as normal. A computer will choose which babies get which treatment. Skin swabs will be taken from various areas of the skin of the babies, and the amount and type of bacteria on these swabs will be counted.

In addition, the skin of the babies will be closely monitored for any signs of side effects to chlorhexidine. Applying an antiseptic can make babies colder and can sometimes cause skin reactions which may make it easier for bacteria to get into the babies instead of protecting them. But the researchers don't know how these different advantages and disadvantages balance out. This study will look at the balance between reducing numbers of bacteria and safety. In the future, the researchers plan to test the best method to reduce the number of bacteria on newborn babies' skin the researchers find in this study in a much larger study, to see whether it could reduce serious infections or not.

What are the possible benefits and risks of participating?
Entering this study may not directly benefit participants. However, the information emerging from the study will help to work out the best way to use chlorhexidine to prevent infections in other babies in the future, as infections remain one of the leading causes of death in the neonatal population.

Where is the study run from?
1. St George's, University of London (UK)
2. Stellenbosch University (South Africa)
3. Child Health Research Foundation, Dhaka Shishu Hospital (Bangladesh)

When is the study starting and how long is it expected to run for?
September 2020 to February 2022

Who is funding the study?
MRC/NIHR/DfID/Wellcome Joint Global Health Trials Call 9 – Trial Development Grant & MRC Core Funding (MRC CTU at UCL) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Study information

Scientific Title
Efficacy and safety of whole-body chlorhexidine gluconate (CHG) cleansing in reducing bacterial skin colonisation of hospitalised neonates: A pilot trial

Acronym
NeoCHG

Study objectives
1. Increasing concentration and frequency of CHG skin application leads to greater reductions in bacterial colonisation.
2. The addition of emollient improves the skin condition and safety of CHG application, permitting the more effective concentration to be used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2020, St George's University of London Research Ethics Committee (Joint Research and Enterprise Services, St George’s, University of London (SGUL), St George’s, University of London, Cranmer Terrace, London SW17 0RE, UK; +44 (0)20 82666073; sgulrec@sgul.ac.uk), ref: 2020.0059

Primary study design
Interventional

Study design
Factorial randomized controlled pilot trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Low birth weight (1-2kg) babies

Interventions
Chlorhexidine gluconate (CHG) whole body skin application in varying concentrations (2% vs 1% vs 0.5%) and varying frequency, each with or without emollient application, compared to a control group with no CHG or emollient. Treatment will continue for 14 days or until discharge. A factorial randomised design is used by this trial, with a 1:1:1:1:1:1:1:1:1:1:1:1:1 allocation into 12 interventions and 1 control arm:
- 0.5% CHG each working day with emollient
- 0.5% CHG each working day without emollient
- 0.5% CHG alternate working days with emollient
- 0.5% CHG alternate working days without emollient
- 1% CHG each working day with emollient
- 1% CHG each working day without emollient
- 1% CHG alternate working days with emollient
- 1% CHG alternate working days without emollient
- 2% CHG each working day with emollient
- 2% CHG each working day without emollient
- 2% CHG alternate working days with emollient
- 2% CHG alternate working days without emollient
- Control Group without emollient and without CHG
(Alternate working days are Monday, Wednesday, Friday; or Tuesday, Thursday, Saturday, depending on the standard working pattern in each country.)

Intervention Type
Other

Primary outcome(s)
Individual follow up during hospital admission up to day 14 after enrolment or discharge if earlier, and final follow up 28 days after enrolment (by phone If already discharged).
1. Skin bacterial load – change in colony forming units (CFUs) in the nose (1 swab), cervical skin folds and umbilicus (1 pooled swab), and peri-rectal area (1 swab) from randomisation (before chlorhexidine application) to D3+/- 1 day and D8 +/- 3 days microbiology data collection (efficacy).
2. Modified neonatal skin condition score used before each application of chlorhexidine, or alternate working days in controls (safety). The primary analysis of this outcome will consider the absolute score. Secondary analysis of this outcome will consider graded toxicity.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
15/02/2022

Eligibility

Key inclusion criteria
1. Aged 1-6 days (post-natally) at enrolment
2. Gestational age ≥28 weeks at birth
3. Birth weight ≥1000g and <2000g (or current weight if unknown)
4. Parental consent
5. Parent’s willingness to avoid routine use of emollients other than those indicated by the randomised allocation

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
208

Key exclusion criteria
1. Poor skin condition (skin score of 2 or more in any of three domains) at the time of enrolment
2. Known congenital or acquired skin disorder or defect at time of enrolment
3. Anticipated length of hospital stay <7 days
4. Chlorhexidine or emollient application determined inappropriate in the opinion of the enrolling clinician

Date of first enrolment
12/04/2021

Date of final enrolment
18/01/2022

Locations

Countries of recruitment
Bangladesh

South Africa

Study participating centre
Stellenbosch University
Private Bag X1
Matieland
Stellenbosch
South Africa
7602

Study participating centre
Child Health Research Foundation
Dhaka Shishu Hospital
Sher-E-Banglanagar
Dhaka
Bangladesh
1207

Sponsor information

Organisation
St George's, University of London

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Research organisation

Funder Name
MRC/NIHR/DfID/Wellcome Joint Global Health Trials Call 9 – Trial Development Grant & MRC Core Funding (MRC CTU at UCL)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the MRC CTU NeoCHG team (mrcctu.neochg@ucl.ac.uk) on reasonable request. Each request will be assessed individually and data released depending on data item variabilities. Copies of the trial CRFs can be provided to applicants. Data will be available for sharing after the trial has reported the primary outcome, and is available on request and pending oversight group review and approval. Data will be shared according to the MRC CTU's controlled access approach, based on the following principles:
1. No data will be released that would compromise an ongoing trial or study.
2. There must be a strong scientific or another legitimate rationale for the data to be used for the requested purpose.
3. Investigators who have invested time and effort into developing a trial or study should have a

period of exclusivity in which to pursue their aims with the data before key trial data are made available to other researchers.
4. Adequate resources must be available in order to comply in a timely manner or at all, and the scientific aims of the study must justify the use of such resources.
5. Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.
Consent from participants was obtained and all data is pseudo-anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/02/2024	01/03/2024	Yes	No
Abstract results	Presented at ECCMID	17/04/2023	18/04/2023	No	No
Protocol file	version 2.0	29/11/2021	30/09/2022	No	No
Statistical Analysis Plan	version 1.0	21/10/2021	30/09/2022	No	No