

# 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

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| <b>Submission date</b><br>07/04/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>18/06/2020 | <b>Overall study status</b><br>Completed          | <input checked="" type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>01/03/2024       | <b>Condition category</b><br>Neonatal Diseases    | <input type="checkbox"/> 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?

Prof. Mike Sharland  
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## Contact information

### Type(s)

Public

### Contact name

Prof Mike Sharland

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## 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

### Study design

Factorial randomized controlled pilot trial

## Primary study design

Interventional

## 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 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  $\geq 28$  weeks at birth
3. Birth weight  $\geq 1000\text{g}$  and  $< 2000\text{g}$  (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 ([mrccctu.neochg@ucl.ac.uk](mailto:mrccctu.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? |
|---|---------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>           |                     | 25/02/2024   | 01/03/2024 | Yes            | No              |
| <a href="#">Abstract results</a>          | Presented at ECCMID | 17/04/2023   | 18/04/2023 | No             | No              |
| <a href="#">Protocol file</a>             | version 2.0         | 29/11/2021   | 30/09/2022 | No             | No              |
| <a href="#">Statistical Analysis Plan</a> | version 1.0         | 21/10/2021   | 30/09/2022 | No             | No              |