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Wound cleaning after C-section: comparing chlorhexidine to saline or sterile water

Submission date
03/12/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Completed

Last Edited
11/12/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Worldwide 21.1% of women gave birth by caesarean ranging from 5% in sub-Saharan Africa to 42.8% in Latin America and the Caribbean. The caesarean delivery rate has risen in all regions of the world since 1990. Projections showed that by 2030, 28.5% of women worldwide will give birth by caesarean. Superficial surgical site (wound) infections can cause suffering and death, and constitute a financial burden and lower quality of life. It is thought that wound infections that occur after planned surgery under a modern clean operating environment are due to a contamination event during the surgery but this belief remains unproven. A sterile postoperative wound could even be infected by a pathogen originating from a site remote from the operative wound (i.e., the Trojan Horse mechanism). Hence post-skin-closure wound cleansing may have a role in minimising the wound infection rate which most often presents 8-10 days after surgery. The National Institute for Health and Care Excellence, UK 2021 guideline on ‘Caesarean birth’ recommends "gently cleaning and drying the wound daily" without mention of a specific cleansing solution, However, their 2019 guideline on general ‘Surgical site infections: prevention and treatment’ recommends to use sterile saline for wound cleansing up to 48 hours after surgery, women may shower safely 48 hours after surgery, and use tap water for wound cleansing after 48 hours. Communicable Disease Center, USA and the World Health Organisation are silent on how to cleanse the Caesarean wound. There is no comparative data on the effect of wound cleansing solutions for after-surgery care on Caesarean wound infection. Wound cleansing is a frequently asked-about subject by mothers. This study aims to find out whether wound cleansing twice a day with 0.05% chlorhexidine alcohol solution (an antiseptic) for 5 days will reduce the occurrence of wound infection (assessed for up to 30 days) compared to using normal saline or water as currently recommended by the National Institute for Health and Care Excellence, UK wound infection prevention guideline (2019).

Who can participate?
Women aged 18 years and above undergoing Caesarean section (planned or unplanned)

What does the study involve?
Participants will be shown and instructed on the wound cleansing process. Cotton wool balls are to be dipped in the allocated solution to saturate the cleaning interface. The ball will then be wiped across the line of the wound in one sweep and then discarded. The skin immediately

above and below the wound line will be similarly cleansed. The cleansed area will be left to air dry. Additional cleansing is permitted if the skin surrounding the wound needs to be cleared of blood or other stains. Scabs are not to be purposefully dislodged. The wound cleansing can be delegated to a helper if needed. The cleansing process is to be done twice daily for 5 days. The cleansing solution provided will be in single-use vials (30 ml) and to be kept below room temperature. Participants will be told they may shower safely 48 hours after surgery using their usual soap including on the area around the wound. The entire body including around the wound shall be dried with the usual clean towel after showering. In the event a patient develops an allergic reaction, they will required to inform the investigators via the number provided in the patient information sheet after which they will be guided further. The patient will also be given the do's and don'ts leaflets on wound management before hospital discharge.

What are the possible benefits and risks of participating?
The possible benefits of participating are better satisfaction with wound healing and cleaning and better wound hygiene. Possible risks include allergic reactions to chlorhexidine.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
May 2023 to October 2024

Who is funding the study?
University of Malaya (Malaysia)

Who is the main contact?
Dr Amsavalli Sundaresan, s2030629@ummc.edu.my (Malaysia)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RSCH ID-23-05955-KD7

Study information

Scientific Title
Chlorhexidine vs normal saline or sterile water for post-operative caesarean section wound cleansing: a randomised controlled trial

Acronym
CNSSW

Study objectives
Application for caesarean wound cleaning of 0.05% chlorhexidine gluconate solution (an antiseptic) compared to normal saline solution or water lowers the risk of superficial surgical site infection.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/11/2023, University of Malaya Medical Centre Medical Research Ethics Commitee (Lembah Pantai, Kuala Lumpur, 59100 , Malaysia; +60 (0)3-79493209/2251; iresearch@ummc.edu.my), ref: 202371-12628

Study design
Parallel group randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Telephone, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cleaning of the caesarean wound in the first 5 days

Interventions
Participants were randomly assigned to the following treatment arms using Block Randomisation:
1. Chlorhexidine (0.05% solution)
2. Normal saline (0.9% sodium chloride solution) or water (50:50 split)

These solutions as allocated will be used to gently wipe the caesarean wound twice a day for 5 days after the surgery.

Intervention Type
Other

Primary outcome measure
The cumulative superficial surgical site infection rates measured by the care provider and by self-reporting through telephone interviews from surgery to 30 days after surgery

Secondary outcome measures
The following secondary outcome measures are assessed by the care provider and by self-reporting through telephone interview (Day 30):
In hospital, evaluation:
1. Before discharge, the wound will be assessed using the CDC criteria for diagnosing superficial surgical site infection by care provider (at hospital discharge)

Measured after hospital discharge by telephone interview:
1. Superficial surgical site infection measured using a telephone-based questionnaire adapted from CDC criteria by self-reporting (Day 15 and 30)
2. Satisfaction with wound healing measured using an 11-point (0-10) numerical rating scale (NRS) by self-grading (Day 15 and 50)
3. Compliance with twice daily wound cleansing in the first 5 days (at least 80% of 10 planned episodes) protocol measured using self-reporting (Day 15)
4. Satisfaction with wound appearance measured using an 11-point (0-10) NRS to rate, by self-grading (Day 30)
5. ‘I will recommend my allocated wound cleansing solution to a friend’ measured using a 5-grade Likert scale (strongly agree, agree, neutral, disagree or strongly disagree response) by self-grading (Day 15)

Overall study start date

20/05/2023

Completion date
19/10/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Caesarean section (CS) (planned or unplanned)
3. Within 24 hours of CS
4. Complete skin closure
5. Access to telephone
6. Can communicate in Malay or English

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
870

Key exclusion criteria
1. Wound issue (gape, discharge, pain, tenderness, redness, swelling, heat)
2. Hypersensitivity or allergy to chlorhexidine
3. Fever (>38°C) in the last 48 hours
4. Chorioamnionitis or suspected chorioamnionitis
5. Wound haematoma or bruising

Date of first enrolment
01/01/2024

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Jalan Profesor Diraja Ungku Aziz, Seksyen 13
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Publication of trial findings in a peer-reviewed medical journal is planned

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author investigator: Dr Amsavalli Sundaresan, S2030629@ummc.edu.my, 6 months after publication of the trial report, subject to review board approval. The type of data that will be shared will include patient data from the data collection sheet, which will be available starting from collection until 25 years post-collection. Consent from participants was required and obtained. Data are anonymized.

IPD sharing plan summary
Available on request