Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of post cesarean wound infection with or without use of hydrogen peroxide during cesarean wound cleaning

Protocol summary

Study aim
The aim of this study is to compare the effectiveness of hydrogen peroxide versus normal saline irrigation in reducing post-cesarean wound infections and promoting faster wound healing.

Design
Randomised, open-label, parallel group controlled trial conducted at a single tertiary care center with a total sample size of 204 participants. Participants were randomly assigned in a 1:1 ratio using a computer-generated sequence to receive either hydrogen peroxide or normal saline wound irrigation. The study was not blinded, and outcome assessment was based on predefined clinical criteria.

Settings and conduct
The trial was conducted at the Department of Obstetrics and Gynecology, JPMC Karachi, over six months. Women undergoing cesarean section were randomized to receive either 3% hydrogen peroxide or normal saline for wound irrigation. Follow-up continued for four weeks to assess wound healing and infection using standardized clinical criteria. The study was open-label with no blinding.

Participants/Inclusion and exclusion criteria
Women aged 18–40 years undergoing cesarean section at >36 weeks and hemodynamically stable were included. Exclusion criteria included chronic illness, active infection, immunocompromised state, or allergy to hydrogen peroxide.

Intervention groups
Participants were randomly assigned to one of two groups. Group A received 3% hydrogen peroxide irrigation of the surgical wound before closure during cesarean section. Group B received normal saline irrigation of the wound before closure. Both groups were followed postoperatively for four weeks to assess wound healing and infection rates.

Main outcome variables
Main outcomes were wound healing time and post-cesarean wound infection. Healing was monitored weekly for four weeks and categorized by duration. Infection was defined by clinical signs such as pus, inflammation, or hematoma.

General information

Reason for update

Acronym
CHIP Trial

IRCT registration information
IRCT registration number: **IRCT20241104063588N2**
Registration date: **2025-05-31, 1404/03/10**
Registration timing: **retrospective**

Last update: **2025-05-31, 1404/03/10**
Update count: **0**

Registration date
2025-05-31, 1404/03/10

Registrant information

Name
Hafiz Sheraz Arshad Arshad

Name of organization / entity
Health and Research Insights

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-01, 1402/10/11

Expected recruitment end date
2024-06-30, 1403/04/10

Actual recruitment start date

2024-01-01, 1402/10/11

Actual recruitment end date

2024-06-30, 1403/04/10

Trial completion date

2024-06-30, 1403/04/10

Scientific title

comparison of post cesarean wound infection with or without use of hydrogen peroxide during cesarean wound cleaning

Public title

comparison of post cesarean wound infection with or without use of hydrogen peroxide during cesarean wound cleaning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged between 18 and 40 years. Undergoing elective or emergency cesarean section. Gestational age greater than 36 weeks. Able and willing to provide informed consent. Agreed to attend postoperative follow-up visits for four weeks. No known allergy to hydrogen peroxide or normal saline. Hemodynamically stable after cesarean delivery.

Exclusion criteria:

Known hypersensitivity or allergy to hydrogen peroxide. Presence of chronic systemic diseases (e.g., chronic obstructive pulmonary disease, stroke, renal or hepatic impairment, malignancies). Patients with ongoing infections at the time of cesarean section. Immunocompromised individuals (e.g., HIV positive, on immunosuppressive therapy). Women with hemodynamic instability postoperatively. Patients with hematological disorders affecting wound healing. Inability to provide informed consent. Refusal or inability to attend follow-up visits for four weeks.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **204**

Actual sample size reached: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used, and the unit of randomization was the individual participant. A computer-generated random number sequence was created using a randomization software to assign participants into two groups: Group A (hydrogen peroxide) and Group B (normal saline). No stratified or block randomization was applied. The random sequence was generated prior to participant enrollment to avoid selection bias. Allocation was concealed using sequentially numbered, opaque, sealed envelopes prepared by a third party not involved in participant recruitment or intervention administration. The envelopes were opened only after a participant was deemed eligible and consented to participate. This process ensured proper allocation concealment and minimized allocation bias.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jinnah Postgraduate Medical Centre, Karachi

Street address

Rafiqui Shaheed Road, Cantt Area, Saddar, Karachi, Sindh, Pakistan

City

Karachi

Postal code

75510

Approval date

2024-01-01, 1402/10/11

Ethics committee reference number

CPSP/REU/OBG-2022-186-12207

Health conditions studied

1

Description of health condition studied

Post-cesarean wound infection and delayed wound healing are common complications following cesarean section. These conditions contribute to increased maternal morbidity, prolonged hospital stays, and higher healthcare costs. This study focuses on evaluating methods to reduce surgical site infections and promote faster wound recovery in postpartum women.

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

Primary outcomes

1

Description

Incidence of post-cesarean wound infection, defined by clinical signs such as pus discharge, inflammation, deep

tissue involvement, or hematoma requiring aspiration, assessed weekly for four weeks after surgery.

Timepoint

48 hours, 1 week, 2 weeks, 3 weeks, and 4 weeks after intervention

Method of measurement

Clinical examination using predefined criteria including presence of pus, redness, swelling, warmth, deep tissue involvement, or hematoma requiring aspiration, performed by trained healthcare professionals during follow-up visits.

Secondary outcomes

1

Description

Wound healing time, categorized as early (<7 days), moderate (7–9 days), or delayed (>9 days), assessed weekly over a four-week postoperative period.

Timepoint

1 week, 2 weeks, 3 weeks, and 4 weeks after intervention

Method of measurement

Clinical assessment of wound healing by trained healthcare professionals, based on visual inspection and categorized as healed within <7 days, 7–9 days, or >9 days, recorded during weekly follow-up visits.

Intervention groups

1

Description

Intervention group: Intervention group: Participants received wound irrigation with 3% hydrogen peroxide solution immediately after cesarean section and before skin closure. The procedure was performed intraoperatively under sterile conditions, and the wounds were subsequently monitored for healing and infection over four weeks.

Category

Treatment - Other

2

Description

Control group: Control group: Participants received wound irrigation with normal saline solution immediately after cesarean section and before skin closure. The procedure was performed intraoperatively under sterile conditions, and the wounds were subsequently monitored for healing and infection over four weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jinnah Postgraduate Medical Centre

Full name of responsible person

Dr Bisma

Street address

Rafiqui Shaheed Road, Cantt Area, Saddar Town, Karachi, Sindh, Pakistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jinnah Postgraduate Medical Center (JPMC)

Full name of responsible person

Dr Bisma

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jinnah Postgraduate Medical Center (JPMC)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Jinnah Postgraduate Medical Centre

Full name of responsible person

Dr Bisma
Position
Trainee
Latest degree
Bachelor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
1. Deidentified Individual Participant Data Set (IPD): Title: Deidentified Participant Dataset for Post-Cesarean Wound Healing and Infection Outcomes Details: This dataset will include deidentified information for all participants enrolled in the trial, including group allocation, age, BMI, comorbidities, cesarean type, wound healing time, and wound infection status. The dataset will be shared in Excel or CSV format and will not contain any personal identifiers. 2. Study Protocol: Title: Study Protocol – Comparison of Hydrogen Peroxide vs Normal Saline in Cesarean Wound Irrigation Details: The full study protocol including background, objectives, methodology, inclusion/exclusion criteria, intervention details, outcome measures, and statistical analysis plan. 3. Statistical Analysis Plan: Title: Statistical Analysis Plan – Cesarean Wound Infection Study Details: This document will describe the statistical tests used (e.g., chi-square test, logistic regression), data handling methods, and software (SPSS v21) used to analyze primary and secondary outcomes. 4. Informed Consent Form: Title: Informed Consent Form – Hydrogen Peroxide vs Saline Wound Irrigation Trial Details: English version of the consent form used to obtain written informed consent from participants, outlining study purpose, procedures, risks, and confidentiality. 5. Clinical Study Report: Title: Final Clinical Study Report – Post-Cesarean Wound Healing Trial Details: The full study report summarizing methodology, results, interpretation, tables, and references, as prepared for publication. 6. Data Dictionary: Title: Data Dictionary for Deidentified Participant Dataset Details: This file will explain variable

names, coding schemes, value ranges, and definitions corresponding to the shared dataset to aid in interpretation by external researchers.

When the data will become available and for how long

The data and documents will become available six months after publication of the study results and will remain accessible for a minimum period of five years. Researchers may request access to the shared files during this time for secondary analyses or validation studies.

To whom data/document is available

The deidentified IPD and supporting documents will be made available to qualified researchers affiliated with academic institutions, healthcare organizations, or research institutions. Requests from individuals in non-academic settings may also be considered if the proposed use is scientifically valid and ethically appropriate.

Under which criteria data/document could be used

Data and documents will be shared for the purpose of academic research, secondary data analysis, or systematic reviews/meta-analyses related to wound care, infection prevention, or obstetric surgical outcomes. Interested researchers must submit a brief proposal outlining the study objectives, methodology, and intended use of the data. Requests will be reviewed by the principal investigator and research team at Jinnah Postgraduate Medical Centre to ensure ethical compliance and scientific validity. Upon approval, data will be shared via secure email or institutional repository under a data-sharing agreement.

From where data/document is obtainable

Requests for data and documents can be made by contacting the Principal Investigator, Dr. Bisma, via email at shaikhsahab553195@gmail.com. Preferred communication is through email. The recruitment center address is Jinnah Postgraduate Medical Centre, Rafiqui Shaheed Road, Cantt Area, Saddar Town, Karachi, Sindh, 75510, Pakistan. For any additional queries, contact can also be made via telephone at +92 21 99201300.

What processes are involved for a request to access data/document

Researchers interested in accessing the data or documents must submit a formal request via email to shaikhsahab553195@gmail.com, including a brief research proposal outlining the objectives, methodology, and intended use of the data. The request will be reviewed by the Principal Investigator and research team at Jinnah Postgraduate Medical Centre. The review process typically takes 2 to 4 weeks. If approved, the requester will be asked to sign a data-sharing agreement to ensure confidentiality and appropriate data use. After agreement, the data or documents will be shared electronically via secure means.

Comments