Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of vaginal prep with chlorhexidine in comparison with normal saline before cesarean section on endometritis and post operative wound infection in the pregnant women undergoing cesarean section

Protocol summary

Study aim

Determining the effect of vaginal lavage with chlorhexidine before cesarean section on endometritis and wound infection after cesarean section

Design

This study is a randomized controlled clinical trial (RCT). The method of random allocation will be block randomization. The minimum sample size in each group was calculated to be 140, and with 15% attrition rate was calculated 160 in each group. Patients during the first 10 days after cesarean section will be examined for symptoms of endometritis (fever 38.8 ° C or higher after 24 hours after surgery) and infection of the incision site (redness or opening of the wound edges with the appearance of purulent discharge).

Settings and conduct

This study was performed in the surgical ward of Kowsar Hospital in Qazvin city in Qazvin province. Blinding: One-way blindness Description of how to blind: Abdominal and vaginal washing will be done in two groups by the researcher. The researcher will be unaware of which group the samples are in.

Participants/Inclusion and exclusion criteria

Inclusion criterion: All mothers who had a cesarean section indication. Non-inclusion criteria: diabetes; Existence of severe chorioamnionitis; Excretion of meconium; Twin pregnancies and more; Prolonged rupture of the bladder (more than 18 hours).

Intervention groups

Intervention group: In addition to rinsing the abdomen with betadine and injecting antibiotics, rinsing with sterile gas containing 0.05% chlorhexidine around and inside the vaginal opening for 45 seconds and rotating 360 degrees will be performed and receive vaginal preparation. Control group: Before starting cesarean section, abdominal rinsing with Betadine and antibiotic injection will be performed. Patients will also receive vaginal lavage with normal saline.

Main outcome variables

Occurrence of endometritis; Abdominal incision site infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050982N1**
Registration date: **2021-05-26, 1400/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-26, 1400/03/05**
Update count: **0**

Registration date

2021-05-26, 1400/03/05

Registrant information

Name

Nasibeh Parsaii athar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3323 6380

Email address

ngo1366@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-29, 1400/02/09

Expected recruitment end date

2022-04-29, 1401/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vaginal prep with chlorhexidine in comparison with normal saline before cesarean section on endometritis and post operative wound infection in the pregnant women undergoing cesarean section

Public title

Effect of vaginal preparation with chlorhexidine before cesarean section on the rate of endometritis and post operative wound infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All pregnant women with cesarean section indication

Exclusion criteria:

Diabetes Chorioamnionitis Severe anemia Meconium excretion Multiple pregnancy (Twin and more) Long-term rupture of bladder (more than 18 hours)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **320**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. To perform this method, the size of each block is specified at first (for example, a quadruple block). Then we write a list of blocks and assign numbers to them. (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then we select random numbers between one and 6 (For example, 1 4 5, etc.) and finally specify the treatment allocation list based on previous random numbers (... AABB-BBAA-BABA-).} The same procedure continues until the sample size is completed. In this way, from among the mothers of 320 people who have the inclusion criteria, they will be selected by convenience and will be divided into two groups of test and control by random block method (160 people in each group).

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that abdominal and vaginal lavage will be performed in two groups by the researcher, endometritis and wound infection will be performed according to the mentioned criteria and the researcher will be unaware of that which sample belongs to each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

5981134197

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.QUMS.REC.1399.490

Health conditions studied

1

Description of health condition studied

endometritis and post operative wound infection in the pregnant women undergoing cesarean section

ICD-10 code

O86.12

ICD-10 code description

Endometritis following delivery

Primary outcomes

1

Description

Occurrence of endometritis

Timepoint

Patients will be evaluated for signs of endometritis (fever 38.8 ° C or higher 24 hours after surgery) during the first 10 days after cesarean section.

Method of measurement

check list

2

Description

Abdominal incision site infection

Timepoint

During the first 10 days after cesarean section, patients will be examined for infection of the incision site

(redness or opening of the wound edges with the removal of purulent discharge).

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to abdominal rinsing with betadine and antibiotic injections, rinsing with 0.05% chlorhexidine-impregnated sterile gas will be performed around and inside the vaginal opening for 45 seconds and rotated 360 degrees to receive vaginal preparation.

Category

Prevention

2

Description

Control group: Before starting cesarean section, abdominal rinsing with Betadine and antibiotic injection will be performed. Patients will also receive vaginal lavage with normal saline.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital, Ghazvin province

Full name of responsible person

Nasibeh Parsaei athar

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Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Qazvin University of Medical Sciences

Full name of responsible person

Nasibeh Parsaei athar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available