

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

**Street address**

Daneshgah Street

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**Postal code**

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Ngo1366@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Nasibeh Parsaei athar

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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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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

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## **Person responsible for updating data**

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**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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