

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of adding vaginal lavage with betadine to routine abdominal lavage on infection after cesarean section

Protocol summary

Study aim

Evaluation of the effect of adding vaginal lavage with betadine to routine abdominal lavage on infection after cesarean section

Design

This study is a non-blinded clinical trial with a parallel design and a control group. The study population will include all women who are candidates for cesarean section referring to Imam Reza hospital in Kermanshah. 170 eligible people will be selected conveniently. Random blocks are used for randomization and participants are assigned to two intervention and control groups .

Settings and conduct

This study is a non-blinded clinical trial. All patients will be prescribed prophylactic antibiotics before the umbilical cord clamp.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women candidates for repeat and non-repeat cesarean section; Singleton; Gestational age of 37 weeks and above Exclusion criteria: Allergy to betadine; Emergency cesarean section Placenta previa, diabetes; Long-lasting labor and mothers undergoing frequent vaginal examinations; AIDS patients

Intervention groups

In the intervention group, in addition to routine washing of the abdominal skin with betadine, vaginal washing with betadine is performed before cesarean section. Rinsing is done with two 10% betadine-soaked gauzes, each of which is rotated 360 degrees inside the vagina so that rinsing the vagina with each gauze will take 30 seconds. Abdominal lavage will be performed with 10% betadine and three betadine-impregnated gauzes. The lavage will begin in a concentric rotation from the abdominal incision and extend from the inside to the outside. The total washing time will be 5 minutes. In the control group, routine abdominal skin washing with 10% betadine and three betadine-impregnated gauzes will be performed.

Main outcome variables

Wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N166**

Registration date: **2021-04-12, 1400/01/23**

Registration timing: **prospective**

Last update: **2021-04-12, 1400/01/23**

Update count: **0**

Registration date

2021-04-12, 1400/01/23

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-20, 1400/01/31

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of the effect of adding vaginal lavage with betadine to routine abdominal lavage on infection after cesarean section

Public title
Evaluation of the effect of adding vaginal lavage with betadine to routine abdominal lavage on infection after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women candidates for repeat and non-repeat cesarean section Singleton Gestational age of 37 weeks and above

Exclusion criteria:
Allergy to betadine Emergency cesarean section Placenta previa, diabetes Disposal of meconium Long-lasting labor and mothers undergoing frequent vaginal examinations AIDS patients Patients with immunosuppressive diseases

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
The permutation random block is used for randomization. In this way, first, the total sample size and the ratio of sample size in groups are determined. Then, the number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block is 0.5. Block 4-0 for the first group and block 5-9 for the second treatment can be used. Based on the selected numbers from the table of random numbers and the determination of blocks, it is clear in which group each person who enters the study will be placed.

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

ir.kums.rec.1399.1139

Health conditions studied

1

Description of health condition studied

cesarean wound complications, such as disruption or infection

ICD-10 code

Y83.8

ICD-10 code description

Other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Wound infection

Timepoint

Beginning of the study, 6 weeks after surgery

Method of measurement

doctor checkup

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, in addition to routine washing of the abdominal skin with betadine, vaginal washing with betadine is performed before cesarean section. Rinsing is done with two 10% betadine-soaked gauzes, each of which is rotated 360 degrees inside the vagina,

so that rinsing the vagina with each gauze will take 30 seconds. Abdominal lavage will be performed with 10% betadine and three betadine-impregnated gauzes. The lavage will begin in a concentric rotation from the abdominal incision and extend from the inside to the outside. The total washing time will be 5 minutes

Category

Treatment - Other

2**Description**

In the control group, routine abdominal skin washing with betadine will be performed. Abdominal lavage will be performed with 10% betadine and three betadine-impregnated gauzes. The lavage will begin in a concentric rotation from the abdominal incision and extend from the inside to the outside. The total washing time will be 5 minutes.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Khadijeh Rahmani

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Khadijeh Rahmani

Position

Resident of Obstetrics and Gynecology

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Anisodoleh Nankali

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Khadigeh Rahmani

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available