Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of vaginal preparation with povidone iodine solution and metronidazole gel on infection after cesarean section

Protocol summary

Study aim
1- Determining and comparing the frequency distribution of fever, cesarean section incision opening, metrites, necrotizing fasciitis, urinary tract infections In the group receiving povidone iodine solution and metronidazole gel and in the control group. 2- Determining and comparing the average length of stay of the mother in the hospital after cesarean section in the group receiving povidone iodine solution and metronidazole gel and in the control group.

Design
This is a randomized clinical trial study with two intervention and one control groups.

Settings and conduct
In the hospital for the first group, 5 gr of metronidazole gel, for the second group, povidone-iodine solution and the third group nothing use for vaginal preparation 15 minutes before surgery. The fever is checked on the first day after surgery.People are checked weekly for up to 6 weeks.They are checked by phone every 3 days

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age at least 24 weeks; being candidate for cesarean section. Exclusion criteria: fever and chorioamnionitis symptoms and signs; thick meconium; admit in labour more than 4 hours; rinse the vagina in labor with antiseptic; HIV positive; manifest diabetes or gestational diabetes; BMI ≥ 30.

Intervention groups
Group 1: Vaginal preparation with metronidazol gel. Group 2: Vaginal preparation with povidon iudine solution. Group 3: Nothing.

Main outcome variables
Fever; cesarean section incision opening; metrites; necrotizing fasciitis; urinary tract infections; length of stay of the mother in the hospital after cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201202049573N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**

Registration date
2020-12-12, 1399/09/22

Registrant information

Name
Parastou Rad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3323 6302

Email address
parastou.rad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-12, 1399/09/22

Expected recruitment end date
2021-04-11, 1400/01/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of vaginal preparation with povidone iodine solution and metronidazole gel on infection after cesarean section

Public title
Comparison of vaginal preparation with povidone iodine solution and metronidazole gel on infection after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
At least gestational weeks should be 22 weeks. Be candidate for cesarean section
Exclusion criteria:
Fever and chorioamnionitis symptoms and signs Thick meconium Admition in labour more than 4 hours Rinse the vagina in labor with antiseptic HIV posetive Manifest diabetes or gestational diabetes BMI ≥ 30
Age
From **15 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **270**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Block Not Matching that there are 3 groups in the present research design, the factorial law of 3 was used for random allocation. Each group was named A, B, C. Then, a random method was used to label each group. Due to having 3 groups of blocks will be as follows: ABC ACB BAC BCA CAB CBA. Write each of the above blocks on a piece of paper and place it so that the content inside it is not clear And every time we start, we choose one of them completely randomly.
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 Yasuj University of Medical Sciences
Street address
Motahhari Boulevard, Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Approval date
2020-10-24, 1399/08/03
Ethics committee reference number
IR.YUMS.REC.1399.146

Health conditions studied

1

Description of health condition studied
Infections after cesarean section
ICD-10 code
O86.0
ICD-10 code description
Infection of obstetric surgical wound

Primary outcomes

1

Description
Cesarean section incision opening
Timepoint
During 6 weeks after surgery
Method of measurement
Examination and observation

Secondary outcomes

1

Description
Fever
Timepoint
The first 24 hours، Once a week for up to 6 weeks
Method of measurement
Thermometer

2

Description
Urinary tract infection
Timepoint
The first 24 hours، Once a week for up to 6 weeks
Method of measurement
First the clinical signs and then the urine test

3

Description
Necrotizing fasciitis
Timepoint
Up to 6 weeks each week
Method of measurement
Clinical signs، Fever

4

Description
Metritis
Timepoint
Up to 6 weeks each week
Method of measurement
Clinical signs، Fever

Intervention groups

1

Description
Intervention group: Vaginal preparation with 5 gr metronidazole gel Before cesarean section by applicator, Up to 15 minutes before cesarean section
Category
Treatment - Drugs

2

Description
Intervention group: Vaginal preparation with Povidone-Iodine solution. Rinse the vagina with a concentrated solution with gas and forceps after insertion of the speculum
Category
Treatment - Drugs

3

Description
Control group: No substance is used
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajad hospital
Full name of responsible person
Parastou rad
Street address
Imam Sajjad Hospital in Yasuj- Next to Azadi Hotel- Yasuj- Kohkilouyeh and Boyer Ahmad
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Phone
+98 74 3322 0163
Email
parastou.rad@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Hossein Marioryad - Vice President for Research
Street address
Yasuj University of Medical Sciences, Motahhari Blvd.
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Phone
+98 74 3323 0290
Email
parastou.rad@gmail.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Parastou Rad
Position
Instructor, Faculty member
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
Department of Midwifery, School of Medicine, next to Imam Sajjad Hospital
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code

7591994799

Phone
+98 74 3323 6302

Email
parastou.RAD@yums.ac.ir

Person responsible for scientific inquiries

Contact

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Yasouj University of Medical Sciences

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data of the participants, the whole study protocol, the whole statistical analysis map, the informed consent form can be shared after not identifying the individuals.

When the data will become available and for how long
3 months after printing the results

To whom data/document is available
For researchers working in academic and scientific institutions

Under which criteria data/document could be used
In medical and surgical fields for the prevention and treatment of infections

From where data/document is obtainable
parastou.rad@gmail.com

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

Comments