

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, metritis, 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 \geq 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; metritis; 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 Admission in labour more than 4 hours Rinse the vagina in labor with antiseptic HIV positive Manifest diabetes or gestational diabetes BMI \geq 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

Kohgiluyeh-va-Boyerahmad

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 Sajad Hospital in Yasuj- Next to Azadi Hotel- Yasuj- Kohkilouyeh and Boyer Ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

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.

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Yasuj

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Kohgilouyeh-va-Boyerahmad

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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

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7591994799

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Person responsible for scientific inquiries

Contact

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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