

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Vaginal preparation with povidone-iodine versus metronidazole for preventing post-Cesarean infections

#### Protocol summary

##### Study aim

Comparison of vaginal preparation with metronidazole gel and povidone-iodine for the prevention of post-cesarean section infections

##### Design

Phase-III single-blind randomized controlled trial with 3 parallel groups on 426 patients, randomization with sealed envelopes

##### Settings and conduct

This study will include pregnant women referred to Shariati Hospital, Bandar Abbas, Iran scheduled for elective cesarean section (CS). Participants will be randomized into 3 groups. The control group will only be prepped (using 7.5% povidone-iodine) and draped. The first intervention group will receive vaginal preparation with metronidazole and the third intervention group 7.5% povidone-iodine in addition to prepping and draping. Patients will be followed up to 15 days after CS. Evaluations will be done by another researcher who is blinded to the grouping of the patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective cesarean section, Singleton pregnancy  
Exclusion criteria: Severe bleeding, Hypersensitivity to povidone-iodine or metronidazole, Active genital herpes, Severe anemia (hematocrit <30%), Human immunodeficiency virus infection, Body mass index >30 kg/m<sup>2</sup>, Preeclampsia, Diabetes mellitus, Antibiotic or corticosteroid use, Rupture of membranes, Chorioamnionitis, Fever due to any cause before cesarean section (temperature >38 C)

##### Intervention groups

Control group: Abdominal skin preparation using povidone-iodine and then draping before C-section;  
Intervention group 1: 10 min to 2 hours prior to C-section, the whole vagina and the anterior and posterior fornixes will be washed in a 360-degree rotational manner for 30 seconds, using povidone-iodine, then prepping and draping before cesarean section.  
Intervention group 2: 2 hours prior to C-section,

metronidazole gel will be used for vaginal preparation, then prepping and draping before cesarean section.

##### Main outcome variables

Endometritis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181218042033N5**

Registration date: **2022-07-15, 1401/04/24**

Registration timing: **retrospective**

Last update: **2022-07-15, 1401/04/24**

Update count: **0**

##### Registration date

2022-07-15, 1401/04/24

##### Registrant information

##### Name

Nazanin Abdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3333 3280

##### Email address

abdinazanin834@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-05-21, 1401/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Vaginal preparation with povidone-iodine versus metronidazole for preventing post-Cesarean infections

**Public title**

Betadine versus metronidazole gel for post-cesarean section infections

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Elective cesarean section Singleton pregnancy

**Exclusion criteria:**

Severe bleeding Hypersensitivity to metronidazole or povidone-iodine Active genital herpes Severe anemia (hematocrit <30%) Human immunodeficiency virus (HIV) infection Body mass index (BMI) >30 kg/m<sup>2</sup> Preeclampsia Diabetes mellitus Antibiotic or corticosteroid use Rupture of membranes Chorioamnionitis Fever due to any cause prior to cesarean section (temperature >38 C)

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **426**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with individuals as units of randomization along with allocation concealment: 426 unclear envelopes and 426 cards with the names of the groups (A, B, C) will be prepared (142 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A, B, or C based on the card inside the selected envelope.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The study will be single-blind, so that the investigator in charge of outcome assessing will be unaware of patient groupings. Therefore, blinding will only be done for the outcome-assessor and the patients, the healthcare providers, and the statistician will know patient groupings.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

**Street address**

Hormozgan University of Medical Sciences, Chamran Blvd., Bandar Abbas, Iran

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916839319

**Approval date**

2021-03-10, 1399/12/20

**Ethics committee reference number**

IR.HUMS.REC.1399.573

**Health conditions studied****1****Description of health condition studied**

Post-cesarean section infection

**ICD-10 code**

O86.12

**ICD-10 code description**

Endometritis following delivery

**Primary outcomes****1****Description**

Endometritis

**Timepoint**

Up to 15 days after cesarean section

**Method of measurement**

Clinical examination

**Secondary outcomes****1****Description**

Wound infection

**Timepoint**

Up to 15 days after cesarean section

**Method of measurement**

Clinical examination

## Intervention groups

### 1

#### Description

Control group: Abdominal skin preparation using 7.5% povidone-iodine (Iran Najo Co., Tehran, Iran) and then draping using sterile surgical drapes before cesarean section

#### Category

Prevention

### 2

#### Description

Intervention group 1: 10 min to 2 hours prior to cesarean section, the whole vagina as well as the anterior and posterior fornices will be washed in a 360-degree rotational manner for 30 seconds, using two pieces of sterile gauze soaked in 7.5% povidone-iodine (Iran Najo Co., Tehran, Iran). Then abdominal skin preparation will be done using 7.5% povidone-iodine and draping using sterile surgical drapes before cesarean section.

#### Category

Prevention

### 3

#### Description

Intervention group 2: 2 hours prior to cesarean section, 5 g metronidazole gel 0.75% (Pars Darou, Iran) will be used for vaginal preparation. Then abdominal skin preparation will be done using 7.5% povidone-iodine (Iran Najo Co., Tehran, Iran) and draping using sterile surgical drapes before cesarean section.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariati Hospital, Bandar Abbas

##### Full name of responsible person

Nazanin Abdi

##### Street address

Dr. Ali Shariati Hospital, Shahid Naser Blvd., Next to the Revolutionary Court, Bandar Abbas, Hormozgan

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7916613885

##### Phone

+98 76 3333 5934

##### Email

abdinazanin834@gmail.com

##### Web page address

<https://dshh.hums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-Chancellery for Research Hormozgan University of Medical Sciences

##### Full name of responsible person

Teamur Aghamolaei

##### Street address

Across from Kargaran Sports Complex, Imam Hossein Blvd., Bandar Abbas, Hormozgan

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919693116

##### Phone

+98 76 3371 0393

##### Email

teaghamolaei@gmail.com

##### Web page address

<https://resv.hums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice-Chancellery for Research Hormozgan 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

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Nazanin Abdi

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Dr. Ali Shariati Hospital, Shahid Naser Blvd., Next to the Revolutionary Court, Bandar Abbas, Hormozgan

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Nazanin Abdi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

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**Position**

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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 further 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**

No - There is not 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