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/m2, 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/m2 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

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

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Phone
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Email
abdinazanain834@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

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+98 76 3333 5934

Email
abdinazanin834@gmail.com

Person responsible for updating data

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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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