Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of metronidazole vaginal gel in reducing surgical site infection in patients undergoing elective hysterectomy

Protocol summary

Study aim
Evaluation of the effect of metronidazole vaginal gel in reducing surgical site infection in patients undergoing elective hysterectomy

Design
Clinical trial without control group with parallel, randomized, phase 3 groups on 70 patients A random number table was used for randomization

Settings and conduct
This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. The first group is treated with metronidazole vaginal cream before surgery and the second group is treated with lubricant vaginal cream. The rate of infection at the surgical site is measured in 2 groups and 6 weeks after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidate for elective hysterectomy surgery, obtaining written consent Exclusion criteria: hysterectomy after cesarean section, hysterectomy after normal delivery, emergency hysterectomies, patients who received broad-spectrum antibiotics before surgery, patient dissatisfaction, patient with vaginitis with cervicitis in the preoperative period

Intervention groups
Intervention group: Patients in this group will be treated with metronidazole vaginal cream daily for three nights before surgery. Then the patients will be operated on and 2 weeks and 6 weeks later, they will be examined for infection at the surgical site. Control group: Patients in this group will be treated daily with lubricant vaginal cream from three nights before surgery. Then the patients will be operated on and 2 weeks and 6 weeks later, they will be examined for infection at the surgical site.

Main outcome variables
Infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200217046523N9**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **prospective**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date
2021-01-15, 1399/10/26

Registrant information

Name
Aryan Rafiee Zadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3837 1582

Email address
rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-28, 1399/11/09

Expected recruitment end date
2021-03-30, 1400/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of metronidazole vaginal gel in reducing surgical site infection in patients undergoing elective hysterectomy

Public title
Metronidazole vaginal gel and surgical site infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for elective hysterectomy Obtaining written consent
Exclusion criteria:
Hysterectomy followed by cesarean section Hysterectomy following a normal delivery Emergency hysterectomies Patients who have received broad-spectrum antibiotics before surgery Patient dissatisfaction Infection of the patient with vaginitis with cervicitis in the preoperative period
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.
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 Esfahan university of Medical sciences
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfehan
Postal code
۸۱۳۷۸۶۶۵۱۵
Approval date
2020-01-03, 1398/10/13
Ethics committee reference number
IR.MUI.MED.REC.1398.498

Health conditions studied

1

Description of health condition studied
Surgical site infection
ICD-10 code
O86.0
ICD-10 code description
Infection of obstetric surgical wound

Primary outcomes

1

Description
Infection
Timepoint
Two weeks and six weeks after surgery
Method of measurement
Examination and patient history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will be treated with metronidazole vaginal cream daily for three nights before surgery. Then the patients will be operated on and 2 weeks and 6 weeks later, they will be examined for infection at the surgical site.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will be treated daily with lubricant vaginal cream from three nights before surgery. Then the patients will be operated on and 2 weeks and 6 weeks later, they will be examined for infection at the surgical site.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Fahime Sabet
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
Dr.fsabet@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
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haghjoo.sh@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fahime Sabet
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Postal code
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Person responsible for scientific inquiries

Contact

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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences
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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after people have requested.
When the data will become available and for how long
Six months after publishing the results.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Scientific uses
From where data/document is obtainable
Isfahan University of Medical Sciences website
What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.
Comments