

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Isfahan

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

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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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Person responsible for updating data

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

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