Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effectiveness of metronidazole plus cefazolin compared to cefazolin alone in reducing surgical siteinfections in women undergoing abdominal hysterectomy and myomectomy

Protocol summary

Study aim

This study aims to compare cefazolin alone with cefazolin plus metronidazole for preventing surgical site infections in women undergoing abdominal hysterectomy or myomectomy.

Design

A randomized, double-blind, two-arm parallel-group clinical trial involving 110 participants, with block randomization.

Settings and conduct

This randomized, double-blind clinical trial will involve 110 women undergoing abdominal hysterectomy or myomectomy at Shariati Hospital, Tehran. Participants will be randomly allocated using block randomization to receive either cefazolin alone or cefazolin plus metronidazole and will be followed up for 14 days to assess infections and other outcomes. Participants, the surgical team, and outcome assessors will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18–60 years; candidates for abdominal hysterectomy or myomectomy; body mass index below 30 kg/m²; written informed consent. Exclusion criteria: Antibiotic use within 14 days; active infection or preoperative fever; immunodeficiency or use of immunosuppressants or corticosteroids; history of radiotherapy; allergy to penicillin or cephalosporins; diabetes; age over 60 years.

Intervention groups

Control group: Cefazolin 2 g intravenously, 30 minutes before surgery. Intervention group: Cefazolin 2 g plus metronidazole 500 mg, both administered intravenously 30 minutes before surgery by the anesthesiologist.

Main outcome variables

Surgical site infection (SSI), including surgical wound infection, urinary tract infection, and vaginal cuff infection. Secondary outcomes: Incidence of postoperative febrile complications, duration of surgery, length of hospital stay, and need for blood transfusion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260707070089N1**
Registration date: **2026-11-10, 1405/08/19**
Registration timing: **prospective**

Last update: **2026-11-10, 1405/08/19**
Update count: **0**

Registration date

2026-11-10, 1405/08/19

Registrant information

Name

Shokouh Molaee zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 910 600 3788

Email address

sh_molaeezamani@razi.tums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-24, 1405/10/03

Expected recruitment end date

2027-05-24, 1406/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of metronidazole plus cefazolin compared to cefazolin alone in reducing surgical siteinfections in women undergoing abdominal hysterectomy and myomectomy

Public title

Comparison of Two Antibiotic Regimens for the Prevention of Infection Following Uterine Surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

age >18 & BMI <30

Exclusion criteria:

Women who had received antibiotics within the previous 14 days. Women older than 60 years. Women with a preoperative infection. Women with preoperative fever Women with immunodeficiency. Women receiving immunosuppressive therapy. Women with a history of radiotherapy. Women with a known allergy to penicillin. Women with a known allergy to cephalosporins. Women taking corticosteroids. Women with diabetes mellitus.

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Procedure Block randomization will be used in this study. Participants will be assigned in blocks of four, with two participants allocated to the intervention group and two to the control group within each block. The allocation sequence within each block will be determined randomly (e.g., AABB, ABAB, BBAA, etc.). The unit of randomization is the individual participant (individual randomization). Each eligible patient will be independently assigned to one of the two study groups, namely, the cefazolin-only group or the cefazolin-plus-metronidazole group, according to the randomization list. Randomization will be performed using a randomization list and a randomization table, which will also be used for the preparation of the medication packages. Generation of the Randomization Sequence The allocation sequence will be generated using block randomization with blocks of four participants. The order of allocation within each block will be determined randomly (e.g., AABB, ABAB, and BBAA). Allocation Concealment To maintain allocation concealment, the study will be conducted using a double-blind design. Medication packages will be prepared in advance according to the randomization table. Each package will contain two syringes of identical volume and appearance. In the control group, the second syringe will contain normal saline, whereas in the intervention group, it will contain 500 mg of metronidazole. The surgical team and outcome assessors will receive only the package number and will remain unaware of the actual contents of the medications and group assignments. Only the individual responsible for preparing the medication packages will have access to the group allocation information. The allocation code will be disclosed only in emergency situations.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind randomized clinical trial. After block randomization, pre-prepared and numbered medication packages will be used. Each package will contain two syringes with identical appearance and volume. In the intervention group, the second syringe will contain metronidazole 500 mg IV, while in the control group, the second syringe will contain normal saline as placebo. Cefazolin will be administered according to the study protocol in both groups before surgery. The patients, surgeons, operating room staff, and outcome assessors will be blinded to the allocated treatment group. Medication preparation and coding will be performed by an independent person who is not involved in patient care or outcome assessment. The randomization code will only be opened in case of an emergency when knowledge of the treatment allocation is medically necessary.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehrna University of Medical Sciences

Street address

No. 100, Qods Street, Enghelab Avenue, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14155-6559

Approval date

2025-11-09, 1404/08/18

Ethics committee reference number
IR.TUMS.SHARIATI.REC.1404.106

Health conditions studied

1

Description of health condition studied
Surgical Site Infection (SSI)Surgical Wound InfectionPostoperative Urinary Tract Infection (UTI)Vaginal Cuff Infection after HysterectomyUterine Leiomyoma (Uterine Fibroid)Abnormal Uterine Bleeding (AUB)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
ncidence of surgical site infection (SSI) within 14 days after abdominal hysterectomy or myomectomy.
Timepoint
The primary outcome (surgical site infection, SSI) will be assessed during the 14-day postoperative follow-up period. Evaluation will include the occurrence of surgical wound infection, urinary tract infection, and vaginal cuff infection after surgery
Method of measurement
The primary outcome will be assessed by clinical examination performed by the research physician evaluation of signs and symptoms of surgical wound infection, examination of the abdominal incision site, vaginal examination for assessment of vaginal cuff infection, evaluation of urinary tract infection symptoms, and recording of vital signs including fever during the 14-day postoperative follow-up period.

Secondary outcomes

1

Description
Occurrence of postoperative febrile complications
Timepoint
Assessed and recorded during the 14-day postoperative follow-up period.
Method of measurement
Assessed by measuring body temperature and monitoring vital signs during hospitalization and postoperative follow-up.

2

Description
Duration of surgery
Timepoint
Measured and recorded from the beginning to the end of surgery.
Method of measurement
Calculated using the recorded operation start and end times documented in the anesthesia or operative report.

3

Description
Length of hospital stay after surgery
Timepoint
Recorded from postoperative admission until hospital discharge.
Method of measurement
Calculated in days based on the admission and discharge dates and times recorded in the patient's medical records.

4

Description
Need for blood transfusion during or after surgery
Timepoint
Assessed and recorded during surgery and the postoperative hospitalization period.
Method of measurement
The occurrence of blood transfusion will be recorded based on the operative report, anesthesia records, and medical records.

5

Description
Requirement for additional postoperative antibiotic therapy
Timepoint
Assessed and recorded during the 14-day postoperative follow-up period.
Method of measurement
The need for additional antibiotic therapy will be recorded based on physician prescriptions and review of medication and medical records.

Intervention groups

1

Description
Participants allocated to the intervention group will receive a single dose of intravenous cefazolin (2 g) in combination with intravenous metronidazole (500 mg), 30 minutes before the start of surgery. The medications used will be manufactured by Abidi Pharmaceutical Company. Both drugs will be administered intravenously by an anesthesiologist. This intervention is intended to prevent surgical site infections in women undergoing abdominal hysterectomy or abdominal myomectomy. The medications will be administered as a single preoperative dose. Both patients and the surgical team will be blinded to the type of medication received.
Category
Treatment - Drugs

2

Description
Control Group: Participants allocated to the control

group will receive a single dose of intravenous cefazolin (2 g), 30 minutes before the start of surgery. The medication will be manufactured by Abidi Pharmaceutical Company. Cefazolin will be administered intravenously by an anesthesiologist for the prevention of surgical site infections in women undergoing abdominal hysterectomy or abdominal myomectomy. Metronidazole will not be administered in this group. Cefazolin will be given as a single preoperative dose. Both patients and the surgical team will be blinded to the type of medication received.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
shokouh molaei zamani

Street address
North Kargar Street, Jalal Al Ahmad Avenue intersection

City
Tehran

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Tehran

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1411713135

Phone
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Email
shariatihosp@tums.ac.ir

Web page address
https://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
somaye moradpanah

Street address
enghelab azar street

City
tehran

Province
Tehran

Postal code
1464665966

Phone
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Email
somayemoradpanah@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
90

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
Tehran University of Medical Sciences

Full name of responsible person
shokouh mollaei zamani

Position
Medical resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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North Kargar Street, Jalal Al Ahmad Avenue intersection, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
shokouh mollaei zamani

Position
Medical resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
shokouh mollaei zamani
Position
Medical resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
North Kargar Street, Jalal Al Ahmad Avenue intersection, Tehran, Iran
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sh_molaeezamani@razi.tums.ac.ir
Web page address
https://shariati.tums.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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