

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

comparison of efficacy of two treatment regimen, cefazolin alone with cefazolin plus metronidazole in the prevention of surgical site infections after hysterectomy

Protocol summary

Study aim

Effect of intravenous cefazolin alone in comparison with cefazolin plus metronidazole in preventing surgical site infections after hysterectomy

Design

A clinical trial with intervention and control group with a sample size of 400 cases, with parallel group, double-blind, randomized clinical trial phase 2-3 during four months of evaluation

Settings and conduct

This randomized double-blind clinical trial is performed on patients undergoing hysterectomy referred to Ayatollah Rouhani Hospital of Babol University of Medical Sciences. In this study, physicians and patients are not aware of the chosen treatment protocol.

Participants/Inclusion and exclusion criteria

All patients undergoing hysterectomy are included in the study. Exclusion criteria in this study included patients with blood disorders (thrombocytopenia), cardiovascular disorders, hepatic disorders with more than 15 seconds of prothrombin time, uncontrolled diabetes and hypertension and any uncontrolled underlying disease that worsened following anesthesia.

Intervention groups

The control group consisted of patients undergoing hysterectomy prophylactic with cefazolin, and the intervention group included patients undergoing hysterectomy prophylactic with cefazolin and metronidazole suppository.

Main outcome variables

postoperative infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046289N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Masomeh Bayani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of efficacy of two treatment regimen, cefazolin alone with cefazolin plus metronidazole in the prevention of surgical site infections after

hysterectomy	
Public title	comparison of efficacy of two treatment regimen,cefazolin alone with cefazolin plus metronidazol in the prevention of surgical site infections after hysterectomy
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: All women who are candidates for hysterectomy Exclusion criteria: Sensitivities to cefazolin Sensitivities to metronidazole sensitivities to penicillins
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 400
Randomization (investigator's opinion)	Randomized
Randomization description	After obtaining informed consent from the patients, they were coded by random numbers that came out of the envelope and patients were divided into control and intervention groups. Then the treatment protocol is performed by the nurse and midwife for both groups. The treatment protocol in this study is as follows: Standard method: Two grams of intravenous cefazolin for the first group (as control group) one hour before surgery and two grams of intravenous cefazolin plus 500 mg metronidazole suppository one hour before surgery in the second group (intervention group).
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, random numbers coded by the head-nurse and midwife are extracted from a pre-prepared envelope by the researcher. Then patients are divided into two groups: control and intervention. Research protocol of the study is performed by the head-nurse and midwife for both groups. The physician and patients are not aware of the chosen treatment protocol.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethic committee of Babol University of Medical Sciences
Street address	Ganjafrooz Ave, Babol, Mazandaran, Iran
City	BABOL
Province	Mazandaran
Postal code	4717647745
Approval date	2019-01-20, 1397/10/30
Ethics committee reference number	IR.MUBABOL.HRI.REC.1397.262
Health conditions studied	
1	
Description of health condition studied	Skin Site Infection after Hysterectomy
ICD-10 code	T81.4
ICD-10 code description	Infection following a procedure
Primary outcomes	
1	
Description	Postoperative infection
Timepoint	Twelve months
Method of measurement	Based on ICD-10 Code criteria description
Secondary outcomes	
1	
Description	Prevention of infection after hysterectomy
Timepoint	Thirty days after the hysterectomy
Method of measurement	Clinical signs of wound infection (redness, swelling, warmth, discharge)
Intervention groups	
1	
Description	Patients who are candidate for hysterectomy receiving

Cefazolin 2gr IV one hour before surgery alone as control group.
Category
Prevention

2

Description
Patients who are candidate for hysterectomy receiving Cefazolin 2gr IV plus Metronidazole 500 mg IV one hour before surgery as intervention group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rohani hospital
Full name of responsible person
Masomeh Bayani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Masomeh Bayani
Position
Associate professor
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Infectious diseases
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available