Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparison of efficacy of two treatment regimen,cefazolin alone with cefazolin plus metronidazol 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

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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 metronidazol 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

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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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