Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of azithromycin prophylaxis on decreasing the rate of post-operative infection in female candidates for elective cesarean section

Protocol summary

Study aim
Evaluation of the effect of azithromycin prophylaxis on decreasing the rate of post-operative infection in female candidates for elective cesarean section

Design
This study is a single-blinded clinical trial with a parallel design and a control group. The study population will include all depressed patients referred to the psychiatric ward of Ayatollah Modarres hospital of Isfahan. The number of 84 eligible patients will be selected conveniently. A random number table is used for randomization and participants are assigned to two intervention and control groups.

Settings and conduct
This study is a single-blinded clinical trial. In such a way that participants are unaware of the allocation of study groups. The two groups will be matched based on age, body mass index, and gravidity. All mothers are given prophylaxis cefazolin of 1 gram within 30-60 minutes before cesarean section.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age over 37 weeks; Selective cesarean section candidates; No history of the previous infection; No sensitivity to the understudy antibiotics Exclusion criteria: Smoker mothers; Corticosteroid users; Pre-pregnancy diabetes; Preeclampsia; Premature rupture of membranes; Gestational diabetes; Mothers taking azithromycin within 7 days of surgery

Intervention groups
The intervention group will receive 500 mg of oral azithromycin manufactured by Farabi company in addition to the standard protocol (cefazolin 1 g, intravenously manufactured by Farabi company). The control group will receive a placebo in addition to the standard protocol (Cefazolin 1 intravenously, manufactured by Farabi company).

Main outcome variables
Wound infection rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N160**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **registered_while_recruiting**

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

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

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of azithromycin prophylaxis on decreasing the rate of post-operative infection in female candidates for elective cesarean section

Public title
Evaluation the effect of azithromycin prophylaxis on decreasing the rate of post-operative infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age over 37 weeks Selective cesarean section candidates No history of previous infection No sensitivity to the under study antibiotics
Exclusion criteria:
Smoker mothers Corticosteroid users Pre-pregnancy diabetes Preeclampsia Premature rupture of membranes Gestational diabetes Mothers taking azithromycin within 7 days of surgery
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
The permutation random block is used for randomization. In this way, first, the total sample size and the ratio of sample size in groups are determined. Then, the number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block is 0.5. Block 4-0 for the first group and block 5-9 for the second treatment can be used. Based on the selected numbers from the table of random numbers and the determination of blocks, it is clear in which group each person who enters the study will be placed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants are unaware of the allocation of study groups. In such a way that the participants, despite their satisfaction and awareness of participating in the study, are unaware of the allocation of study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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Province
Kermanshah
Postal code
6715847141
Approval date
2020-12-22, 1399/10/02
Ethics committee reference number
IR.KUMS.REC.1399.872

Health conditions studied

1

Description of health condition studied
Infection following cesarean section
ICD-10 code
T81.4
ICD-10 code description
Infection following a procedure

Primary outcomes

1

Description
Wound infection rate
Timepoint
From the time of hospitalization to the time of stitches removal, the first week after surgery and 6 weeks after surgery
Method of measurement
Asking from the patient

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 500 mg of oral azithromycin manufactured by Farabi company in addition to the standard protocol (cefazolin 1 g, intravenously manufactured by Farabi company).
Category
Treatment - Drugs

2

Description
The control group will receive a placebo in addition to the standard protocol (Cefazolin 1 intravenously, manufactured by Farabi company).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Maryeh Rezaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kermanshah 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
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Full name of responsible person
Maryeh Rezaei
Position
Resident of Obstetrics and Gynecology
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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
No - There is not 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
Not applicable