Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of prophylactic administration of cefazolin, ampicillin and azithromycin in prevention of postpartum infections after cesarean

Protocol summary

Summary

The purpose of this study was to compare the prophylactic administration of cefazolin , ampicillin and azithromycin in the prevention of postpartum infections after cesarean. A total of 375 patients with non-elective cesarean candidates are placed randomly in three groups of 125 individuals. Inclusion criteria include non-elective caesarean section women candidates, gestational age 28 weeks or more. Exclusion criteria are hypersensitivity to cefazolin or ampicillin, or azithromycin; unwillingness patient; received systemic antibiotics within 2 weeks, prior cesarean delivery fever, PROM more than 18 hours, chorioamnionitis; receiving immunosuppressive drugs, the risk of diseases such as diabetes and immune deficiency: liver disease, kidney disease and heart failure or pulmonary edema active, have multiple pregnancies, preeclampsia, urinary tract infection or pneumonia, duration greater than one hour during subcutaneous drains. First group receive 2 g of cefazolin in 30 to 60 minutes before cutting. Second group receive regimen of 2 g of cefazolin in 30 to 60 minutes before cutting + 500 mg intravenous azithromycin and third group receive regimen of ampicillin 2 g in 30 to 60 minutes before cutting + 500 mg intravenous azithromycin. Determine the incidence of puerperal infection after cesarean section in all 3 groups at discharge, 2-week and 6-week and hospitalization period is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080710511N2**
Registration date: **2013-08-21, 1392/05/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-21, 1392/05/30

Registrant information

Name

Maryam Karamali

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-10-11, 1391/07/20

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic administration of cefazolin, ampicillin and azithromycin in prevention of postpartum infections after cesarean

Public title

Comparison of prophylactic administration of cefazolin, ampicillin and azithromycin in prevention of postpartum infections after cesarean

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were: Non-elective Caesarean section women candidates; Gestational age of 28 weeks and more. Exclusion criteria were: Sensitivity to cefazolin or ampicillin or azithromycin; Unwillingness of patients; Received systemic antibiotics within 2 last weeks; Fever prior cesarean; PROM more than 18 hours; chorioamnionitis; Receiving immunosuppressive drugs; Diseases such as diabetes and immune deficiency: liver disease, kidney disease and heart failure or pulmonary edema; multiple pregnancies; preeclampsia; Urinary tract infection or pneumonia; Operation for more than an hour; Intraoperative subcutaneous drains; Abnormal adherence of the placenta to be observed during operation; Elective caesarean; Diarrhea at the time of delivery; Any patient with significant electrolyte disturbances such as hypokalemia, hypocalcemia.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **375**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak, Sardasht, Arak University of Medical Sciences

City

Arak

Postal code

Approval date

2012-08-13, 1391/05/23

Ethics committee reference number

91-130-11

Health conditions studied

1

Description of health condition studied

postpartum infection

ICD-10 code

085-092

ICD-10 code description

Complications predominantly related to the puerperium

Primary outcomes

1

Description

postpartum infection

Timepoint

Discharge, 2 weeks and 6 weeks after surgery

Method of measurement

Fever, abdominal pain, uterine tenderness, erythema, and purulent discharge from the wound

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Study duration

Method of measurement

Medical record

Intervention groups

1

Description

receiving routine prophylactic (cefazolin 2 g of 30 to 60 minutes before cutting)

Category

Prevention

2

Description

regimen of 2 g of cefazolin in 30 to 60 minutes before cutting + 500 mg intravenous azithromycin

Category

Prevention

3

Description

regimen of ampicillin 2 g in 30 to 60 minutes before cutting + 500 mg intravenous azithromycin

Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Taleghani Hospital
Full name of responsible person
Dr. Maryam Karamali
Street address
Arak, Emam Khomeini Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Saeid Ashtiani
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Arak, Sardasht, Arak University of Medical Sciences
City
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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
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty