Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between prophylactic cefazolin regimen with or without azithromycin on the incidence of cesarean site infection in Alzahra hospital of Tabriz

Protocol summary

Summary

From September 2014 to January 2016, women who undergo elective and non-elective caesarean section in Alzahra hospital will be studied. Exclusion criteria are immune deficiency; renal failure; women with two out of four SIRS (systemic inflammatory response syndrome) criteria [1)body temperature above 38 or below 36 degree 2)pulse rate above 90 per minute 3)respiratory rate above 20 per minute 4)WBC above 12000 or below 4000]; hypersensitivity to cefazolin or azithromycin; patient who have received antibiotics in the past three months; diabetics. For enrolling patient in group A, cefazolin, or group B, cefazolin plus azithromicin, we will use random table number and blocked randomization. Patient in group A will receive a single dose IV 1g cefazolin after clamping umbilical cord. In group B, they will receive the same IV 1g cefazolin, plus 2 pills of azithromicin (250mg) from Keyhandaroo Company, Iran made, when they are able to intake by mouth. After selecting patient, they will receive complete information about the study and the method by attending physician or resident. If they accept to check the informed consent they will enter the study. After that, the study checklist about demographic information, obstetrics and gynecology, present pregnancy, past history of wound infection will be completed. Routine clinical information like pre intra and post-operative vital signs will be recorded to the time of discharge. Also the operative field will be checked for infection. The patients are requested to come back 10 days and one month later for follow up. In this study we will evaluate the incidence of cesarean site wound infection, endometritis and other infections, duration of hospitalization, and cost.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510265485N5**
Registration date: **2015-12-06, 1394/09/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-06, 1394/09/15

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison between prophylactic cefazolin regimen with or without azithromycin on the incidence of cesarean site infection in Alzahra hospital of Tabriz

Public title
The effect of adding azithromycin to routine prophylactic regimen on the incidence of cesarean surgical site infection
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criterion: women who underwent elective and non-elective Cesarian section. Exclusion criteria: immune deficiency; renal failure; women with two out of the four SIRS (systemic inflammatory response syndrome) criteria [1)body temperature above 38 or below 36 degree 2)pulse rate above 90 per minute 3)respiratory rate above 20 per minute 4)WBC above 12000 or below 4000]; hypersensitivity to cefazolin or azithromycin; patient receiving antibiotic in the past three months; diabetics.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
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
Ethics Committee of Tabriz University of Medical Scienses
Street address
Research Deputy of Tabriz University of Medical Scienses, University of Tabriz, Golgasht street
City
Tabriz
Postal code
5138665793
Approval date
2015-11-21, 1394/08/30
Ethics committee reference number
tbzmed.rec.1394.696

Health conditions studied

1

Description of health condition studied
wound infection
ICD-10 code
O86.0
ICD-10 code description
Infected: caesarean section wound

2

Description of health condition studied
post cesarian endometritis
ICD-10 code
O86.8
ICD-10 code description
Other specified puerperal infections

Primary outcomes

1

Description
Incidence of cesarean site wound infection
Timepoint
Before, in the current and immediately after, one day and ten day after the operation
Method of measurement
Vital sign and physical examination

2

Description
Incidence of endometritis
Timepoint
Before, in the current and immediately after, one day and ten day after the operation
Method of measurement
Vital sign and physical examination

Secondary outcomes

1

Description
Cost
Timepoint
Ten day after discharge
Method of measurement
Rate of payment

2

Description
Duration of hospitalization
Timepoint
Ten day after operation
Method of measurement
Days of hospitalization

Intervention groups

1

Description
Patient in control group will receive the routine prophylactic single dose of 1g cefazolin IV, after clamping umbilical cord.
Category
Prevention

2

Description
1g IV cefazolin after clamping umbilical cord, plus 2 pills of azithromicin (250mg) from Keyhandaroo Company, Iran made, when they are able to intake by mouth.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra and Talegani Hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Elahe Saheb Olad Madarec
Street address
Tabriz University of Medical Sciencesi, Artesh street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Health Research Center, Tabriz 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

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nazli Navali
Position
associate professor/bord certificate of obstetrics and gynecology
Other areas of specialty/work
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Person responsible for updating data

Contact

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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