

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 azithromycin, 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 azithromycin (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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+98 41 1330 2879

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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 Cesarean 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 Sciences

Street address

Research Deputy of Tabriz University of Medical Sciences, 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 azithromycin (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 Sciences, 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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Web page address

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