Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of cefazolin and cefazolin plus azithromycin regimens in prevention of infection in caesarean section in Shahid Sayyad Shirazi hospital , 2017-2019

Protocol summary

Study aim

Determining the effect of two cefazolin prophylaxis regimens alone and cefazolin plus azithromycin in the prevention of infections caused by cesarean delivery at Shahid Sayyad Shirazi Hospital.

Design

To randomize the first sample, the azithromycin group receiving cefazolin and the second sample will be assigned to the cefazolin group, and this process will proceed to the end of the sampling. An individual who compares the results of the two groups is unaware of the type of intervention. The final sample size was 125 in each group. A total of 250 people will be included in the study.

Settings and conduct

In this study, pregnant women over 18 years of age with a gestational age greater than 28 weeks plus Premature Rupture of Membranes (PROM) who will undergo emergency cesarean delivery at Shahid Sayyad Shirazi Hospital during the years 2017-2109 will be included. Pregnant women with inclusion criteria were randomly divided into two groups: 1) the group receiving azithromycin and cefazolin before surgery; 2) the group receiving cefazolin before surgery; then, the two groups matched the gestational age and the PROM They will be.

Participants/Inclusion and exclusion criteria

Pregnant women over 18 years of age with a gestational age greater than 28 weeks plus PROM or PPROM who will be placed at the Shaheed Sayyid Shiraz Hospital during the delivery of emergency cesarean section during 2017-2017.

Intervention groups

The group received a single dose of 500 mg oral azithromycin plus 2 g intravenous cefazolin and another 2 g intravesical cefazolin half an hour before surgery.

Main outcome variables

the rate of infection of the cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190609043847N1**
Registration date: **2019-07-23, 1398/05/01**
Registration timing: **retrospective**

Last update: **2019-07-23, 1398/05/01**
Update count: **0**

Registration date

2019-07-23, 1398/05/01

Registrant information

Name

Zeinab Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3225 0621

Email address

dr.jalali.z@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

2017-11-21, 1396/08/30

Actual recruitment end date

2019-04-20, 1398/01/31

Trial completion date

2019-04-20, 1398/01/31

Scientific title
Comparison of cefazolin and cefazolin plus azithromycin regimens in prevention of infection in caesarean section in Shahid Sayyad Shirazi hospital , 2017-2019

Public title
Prevention of post-cesarean infection
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Female candidates for non-elective cesarean section, gestational age of 28 weeks and more, no history of infection before surgery, no use of any antibiotic within a week, no use of any antibiotic other than the antibiotics studied, no history Allergy to any medication preterm rupture of membranes less than 24 hours.
Exclusion criteria:
Sensitivity to cefazolin or azithromycin Patient unwillingness Get systemic antibiotic in the last 2 weeks Fever prior to cesarean delivery Preterm rupture of membranes more than 24 hours. Get Immunosuppressive Drugs Diseases such as diabetes and immune deficiency Liver disease Kidney and heart failure or pulmonary edema multiple pregnancy pre-eclampsia urinary tract infection or pneumonia Duration of surgery for more than an hour the insertion of subcutaneous ducts during surgery, Abnormal adhesion of placenta
Age
From **18 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **250**
Actual sample size reached: **250**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the first sample, the azithromycin group receiving cefazolin and the second sample will be assigned to the cefazolin group, and this process will proceed to the end of the sampling. An individual who compares the results of the two groups is unaware of the type of intervention.
Blinding (investigator's opinion)
Not 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 Golestan University of Medical Sciences
Street address
No. 4, Boali Ave., Pasdaran Blve, Gorgan
City
Gorgan
Province
Golestan
Postal code
4916673353
Approval date
2018-02-25, 1396/12/06
Ethics committee reference number
IR.Goums.REC.1396.285

Health conditions studied

1

Description of health condition studied
Infection caused by cesarean delivery
ICD-10 code
O86.0
ICD-10 code description
Infection of obstetric surgical wound

2

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

Primary outcomes

1

Description
the incidence of post-cesarean infection
Timepoint
Infection is recorded two to ten days after admission.
Method of measurement
The secretion, erythema, and severe swelling of the site, as well as persistent fever, are checked

Secondary outcomes

empty

Intervention groups

1

Description

The first group received cefazolin 2 g in 30 minutes before cutting

Category

Prevention

2

Description

The second group received 2 grams in 30 minutes of cefazolin before cutting + 500 mg of oral Azithromycine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi hospital

Full name of responsible person

Zeinab Jalali

Street address

No. 4, Boali Ave, Pasdaran Blve, Gorgan.

City

Gorgan

Province

Golestan

Postal code

4916673353

Phone

+98 17 3225 0621

Email

dr.jalali.z@goums.ac.ir

Web page address

http://goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohamad Reza Honarvar

Street address

Gorgan University of Medical Sciences, Hirkan Blve, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 0021

Email

gsm@goums.ac.ir

Web page address

http://goums.ac.ir/content/1023/%D8%AF%D8%A7%D9%86%D8%B4%DA%A9%D8%AF%D9%87-%D9%BE%D8%B2%D8%B4%DA%A9%DB%8C-%DA%AF%D8%B1%DA%AF%D8%A7%D9%86

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Zeinab Jalai

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 4, Boali Ave, Pasdaran Blve, Gorgan.

City

Gorgan

Province

Golestan

Postal code

4916673353

Phone

+98 981732250621

Email

dr.jalali.z@goums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Zeinab Jalai

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No.4, Boali Ave, Pasdaran Blve, Gorgan

City

Gorgan

Province

Golestan

Postal code

4916673353

Phone

+98 17 3225 0621

Email

dr.jalali.z@goums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Zeinab Jalali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 4, Boali Ave, Pasdaran Blve, Goragn

City

Gorgan

Province

Golestan

Postal code

4916673353

Phone

+98 17 3225 0621

Email

dr.jalali.z@goums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome can be shared.

When the data will become available and for how long

Get started 9 months after printing results

To whom data/document is available

Results will only be available to researchers at university institutes and students.

Under which criteria data/document could be used

Data usage is not a problem if the source is mentioned.

From where data/document is obtainable

آدرس پست الکترونیک

What processes are involved for a request to access data/document

The request will be sent by email and the email will be sent to the data.

Comments