

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of combined antibiotic regimen of cefazolin and azithromycin in comparison with cefazolin antibiotic regimen on the incidence of non-emergency cesarean section infection

Protocol summary

Study aim

Comparison of the incidence of non-emergency cesarean section infection between the two groups receiving prophylaxis regimen of cefazolin and azithromycin with cefazolin regimen in pregnant women referred to Mahdih Hospital

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 204 patients. Excel software rand function was used for randomization.

Settings and conduct

The study is performed on non-emergency cesarean section patients of Mahdih Hospital in Tehran. Patients are randomly divided into two groups and receive antibiotics before surgery. There are two blinds and the patient, surgeon and researcher do not know about the medicine received.

Participants/Inclusion and exclusion criteria

Inclusion criteria include pregnant women who are candidates for non-emergency cesarean section. Exclusion criteria include: 1- Patients unwilling to participate.

Intervention groups

Control group: take cefazolin 30 to 60 minutes before skin incision. Intervention group: In addition to cefazolin, take 500 mg intravenous azithromycin 30 to 60 minutes before skin incision.

Main outcome variables

Comparative study of the prevalence of cesarean section infection in the control and intervention groups, which is determined as any symptoms of surgical site infection such as fever, chills, erythema, and evidence of cellulite and discharge at the surgical site.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220223054104N1**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

Mahsa Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4483 4648

Email address

mahsaeskandariuni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-09-10, 1401/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of combined antibiotic regimen of

cefazolin and azithromycin in comparison with cefazolin antibiotic regimen on the incidence of non-emergency cesarean section infection

Public title

cesarean section site infection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All women candidate for elective cesarean section in Mahdie hospital

Exclusion criteria:

Patients who do not consent to participate in the study.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization, with Random Number Generation computer software A random number is a number chosen from a pool of limited or unlimited numbers that has no discernible pattern for prediction. The pool of numbers is almost always independent from each other. However, the pool of numbers may follow a specific distribution. For example, the height of the students in a school tends to follow a normal distribution around the median height. If the height of a student is picked at random, the picked number has a higher chance to be closer to the median height than being classified as very tall or very short. The random number generators above assume that the numbers generated are independent of each other, and will be evenly spread across the whole range of possible values. A random number generator, like the ones above, is a device that can generate one or many random numbers within a defined scope. Random number generators can be hardware based or pseudo-random number generators. Hardware based random-number generators can involve the use of a dice, a coin for flipping, or many other devices.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is two-blind and patients, surgeons and researchers themselves will not know which group the patient is in. After randomization using the software, neither the patient nor the researcher knew which group the patient was in, and whether or not they were to receive azithromycin preoperatively.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid beheshti University of Medical Sciences

Street address

Shahid beheshti medical university, Koodakiar street, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-03-11, 1400/12/20

Ethics committee reference number

IR.SBMU.MSP.REC.1400.781

Health conditions studied**1****Description of health condition studied**

Surgical site infection

ICD-10 code

T81.4XXA

ICD-10 code description

Infection following a procedure, subsequent encounter

Primary outcomes**1****Description**

Incidence and prevalence of cesarean section site infection

Timepoint

From the time of cesarean section until 30 days later

Method of measurement

Clinical evidence and signs of surgery site infection including fever and chills, erythema, warmth, tenderness, swelling, purulent discharge from the incision site, uterine tenderness and purulent vaginal discharge 24 and 48 hours after surgery and on days 10 and 30 after The action is evaluated by the researcher.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients will have a bath with antibacterial soap the night before the operation, and the hair on the area before the operation and before the operation will be cut with scissors for all patients, and the vital signs of the patients will be recorded before the operation. In the experimental group, in addition to intravenous cefazolin, based on the appearance of body mass before pregnancy or early pregnancy (for the appearance of body mass less than 30, two grams of cefazolin and for the appearance of body mass more than 30, three grams of cefazolin) as a bolus infusion 30 to 60 Minutes before skin incision, 500 mg intravenous azithromycin will be given as a continuous infusion for 30 to 60 minutes. It should be noted that the dose of azithromycin is the same in all patients with different body mass profile and only the dose of cefazolin will be adjusted based on body mass profile. In addition, in patients with a body mass index of more than 30, if the duration of the operation is more than one and a half hours, the patient's intravenous dose of cefazolin will be repeated. It is not an action. In patients with a body mass index of less than 30, the dose of the antibiotic cefazolin will be repeated if the duration of the operation is more than 3 hours. In the operating room, the third degree of obstetrics and gynecology assistants is performed with the same technique, and in all operations, hand washing is performed with the same technique and chlorhexidine solution by scrub, circular and surgeon. Also, for all patients with peripheral abdominal skin, iodine solution is infused at the surgical site. Skin incisions are made in all patients with a scalpel and no catheter is used during the operation for any of the patients. Also, after the placenta is removed, the placenta is removed by applying a gentle stretch to the umbilical cord and the uterus will be swiped with two sterile gases. The peritoneum will be repaired with zero vicryl yarn and the fascia will be repaired with zero nylon as a continuum. And the tissue under the skin, if it is more than two centimeters thick, is approached with three zeros with vicryl thread, and the skin is repaired with two zeros with nylon thread as a continuum, and finally the incision is bandaged. It should be noted that the duration of the operation, the type of patient incision and vital signs will be recorded by the researcher in the questionnaire. After the operation, patients are transferred to the post-part ward and those who need ICU hospitalization are excluded from the study. In all patients in the first 24 hours of surgery based on body mass profile, intravenous cefazolin ampules will be administered every 6 hours up to 3 doses. For all patients, the dressing will be removed after 24 hours and patients will be treated within 48 hours after surgery. Surgery site infections include fever and chills, erythema, warmth, tenderness, swelling, purulent discharge from the incision site, uterine tenderness, and purulent vaginal discharge. In case of symptoms of infection, a complete evaluation is done until treatment. Patients are discharged without symptoms and are

followed up by a researcher at the clinic 10 days after surgery. At the time of referral, fever, chills, erythema, warmth, tenderness, swelling, purulent discharge from the incision, uterine tenderness, and purulent vaginal discharge are evaluated. If there is evidence of infection, follow-up is done until complete treatment. Otherwise, 30 days after the operation, they will be followed up again by referring to the clinic for signs of infection, and then the rate of infection will be determined in both groups. The two groups will be compared.

Category

Prevention

2

Description

Control group: All patients will have a bath with antibacterial soap the night before the operation, and the hair on the area before the operation and before the operation will be cut with scissors for all patients, and the vital signs of the patients will be recorded before the operation. In the control group, intravenous cefazolin based on the appearance of body mass before pregnancy or early pregnancy (for the appearance of body mass less than 30, two grams of cefazolin and for the appearance of body mass more than 30, three grams of cefazolin) as a bolus infusion 30 to 60 minutes before it will be prescribed from the skin incision.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie hospital

Full name of responsible person

Mahsa Eskandari

Street address

Shousha Square, Fadaeian Islam St., Shishegarhaneh Alley, Iran, Tehran,

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

Mahsaeskandariuni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid beheshti university of medical sciences,
Koodakiar, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Eskandari

Position

Specialty assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 46, Nastaran alley, Simonbolivar Ave, North
Janatabad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 4483 4648

Fax

Email

mahsaeskandariuni@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Eskandari

Position

Specialty assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 46, Nastaran alley, Simonbolivar Ave, North
Janatabad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 4483 4648

Fax

Email

mahsaeskandariuni@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Eskandari

Position

Specialty assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 46, Nastaran alley, Simonbolivar Ave, North
Janatabad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 4483 4648

Fax

Email

mahsaeskandariuni@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the consequences considered in the study can be shared.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available

All researchers in academia and industry can access the information in this trial.

Under which criteria data/document could be used

The data of this study can be used for meta-analysis in future studies.

From where data/document is obtainable

Applicants must send an email in English to the email address of Mahsa Eskandari, the project manager.
mahsaeskandariuni@gmail.com

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

An email in English containing the required information will be sent to the lead developer and the reason for the need and the location of the information will be reported to them. Within 10 working days of sending the email, the review request and information will be provided in the form of an email.

Comments