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 Mahdieh 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 Mahdieh 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 participitate.

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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

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Position
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Latest degree
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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