

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison between azithromycin and cephalexin for preventing infection after cesarean section in obese patients

Protocol summary

Summary

This study is a clinical trial of 231 pregnant women undergoing elective Caesarean section in Mordad 1391 from Bandar Abbas in Persian date Mordad 1392 Shariati Hospital were enrolled. The use of azithromycin and cephalexin antibiotic to prevent infection and reduce hospital stay following cesarean section in obese patients. Inclusion criteria: pregnant women with more than fourteen years of age; BMI over thirty; thirty-seven weeks of pregnancy; and the Indications for elective cesarean section. Exclusion criteria: Pregnant women with a history of diabetes; Hypertension; Connective tissue diseases; History of PROM; Twin; Antibiotic therapy. Control group received 2 g IV Keflin half hour before surgery for antibiotic prophylaxis and 48 hours after C/S, 500 mg every 6 hours cephalexin placebo and 250 mg azithromycin placebo was administered every 12 hours for them. The intervention group as the control group received, 2 g IV Keflin half hours before surgery for antibiotic prophylaxis and 48 hours after C/S, 500 mg every 6 hours cephalexin and 250 mg every 6 hours with 250 mg azithromycin every 12 hours was prescribed for them. Patients within 48 hours of hospitalization and up to one month after the c-section out of any fever, endometritis, wound infection, and symptoms were monitored and followed up. During this month, the clinic had any fever or infections were seen at the end of the month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041017212N1**

Registration date: **2014-06-16, 1393/03/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

Maryam Abbasian

Name of organization / entity

Hormozgan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between azithromycin and cephalexin for preventing infection after cesarean section in obese patients

Public title

Reduction of infection after caesarean section in obese women with antibiotic prophylaxis

Purpose

Prevention

Inclusion/Exclusion criteria

In this study, 222 pregnant women aged over 14 years; BMI > 30; with a gestational age of 37 weeks or older; who are undergoing elective cesarean section; can be selected. Exclusion criteria included: pregnant women aged over 14 years; BMI > 30; with a gestational age of 37 weeks or older; who are undergoing elective cesarean section with a history of diabetes; HTN; history of connective tissue diseases; and PROM; twin; antibiotics therapy during recent weeks. Initially weight - height and BMI calculated and those with BMI > 30 were selected and randomly divided into two groups. Both intervention group and control group in terms of demographic characteristics, duration of surgery, surgical techniques are the same.

Age

From **14 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **222**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Sciences

Street address

Shahid Naser Ave., Dr Shariati Hos., Bandar abbas

City

Bandar Abbas

Postal code

Approval date

2012-11-26, 1391/09/06

Ethics committee reference number

HEC-91-9-6

Health conditions studied

1

Description of health condition studied

Elective caesarean section in obese women

ICD-10 code

O82.8

ICD-10 code description

Other single delivery by caesarean section

Primary outcomes

1

Description

Infection after surgery

Timepoint

after C/S, 1 week, 2 weeks, 3 weeks and 4 weeks after C/S

Method of measurement

Observe

Secondary outcomes

empty

Intervention groups

1

Description

This prospective , randomized study of 231 pregnant women undergoing elective cesarean section from Mordad 1391 Persian date to Mordad 1392 from Bandar Abbas, Shariati Hospital was performed. The intervention group the same as control group received 2 g Keflin IV half an hour before surgery, and after surgery cephalixin 500 mg P.O. every 6 hours for 48 hours with 250 mg azithromycin P.O. every 12 hours was prescribed for them.

Category

Treatment - Drugs

2

Description

This prospective , randomized study of 231 pregnant women undergoing elective cesarean section from Mordad 1391 Persian date to Mordad 1392 from Bandar Abbas, Shariati Hospital was performed. Control group received 2 g IV Keflin half hour before surgery for antibiotic prophylaxis and 48 hours after C/S, 500 mg every 6 hours cephalixin placebo and 250 mg azithromycin placebo was administered PO every 12 hours for them .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariati Hos.

Full name of responsible person

Dr. Maryam Abbasian

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr. Maryam Azizi

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Grant name

N/A

Grant code / Reference number

N/A

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

Yes

Title of funding source

DR Maryam Azizi

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**

Dr. Shariati Hospital

Full name of responsible person

Maryam Abbasian

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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