

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of differences in post-cesarean section infection following three-dose prophylactic regimen with no prescription of antibiotics

Protocol summary

Study aim

The effect of antibiotic administration on prevention of post-cesarean infection

Design

A randomized, double-blind, clinical trial, parallel group

Settings and conduct

In this study, patients were divided into two groups of three doses of antibiotics and no antibiotics. Simple randomization is used for this study and the effect of these two regimens on preventing post-cesarean section infection was evaluated.

Participants/Inclusion and exclusion criteria

All patients undergoing elective cesarean section at Sarem Specialty Hospital are included in the study.
Inclusion criteria: In this study only women who had elective cesarean section without any indication of risk
Exclusion criteria: In this study, women with diabetes, preeclampsia, obesity and BMI over 30, abdominal wall enlargement, etc. Or their cesarean section with any reason is longer than usual, such as placenta adhesion.

Intervention groups

Group 1: They receive three doses of antibiotics after surgery. Group 2: They do not receive any antibiotics after surgery.

Main outcome variables

Determination of wound infection rate in cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190902044667N1**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

Registration date

2019-11-13, 1398/08/22

Registrant information

Name

Mozhgan Karamnia Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 0883

Email address

dr.karamnia@saremhospital.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of differences in post-cesarean section infection following three-dose prophylactic regimen with no prescription of antibiotics

Public title

Antibiotic prescription after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women who have had elective caesarean section without

any risky indication
Exclusion criteria:
History of diabetes, preeclampsia, obesity and BMI over 30
Prolonged cesarean section is longer than usual

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used to perform this study and by throwing dice.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the national protocol prescribing an antibiotic dose one hour before surgery is essential for all patients. The design of the study is that all patients undergoing elective caesarean section in the Sarem Specialty Hospital will be conducted as a single-blind study. Data collection and analysis will be done by the statistician who does not have any information about the intervention and control groups. Patients are divided into two groups: Group 1: They receive three doses of antibiotics after surgery. Group 2: They do not receive any antibiotics after the operation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hemat Highway next to MMilad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.IUMS.REC.1396. 23099608822

Health conditions studied

1

Description of health condition studied

Antibiotic prescription after cesarean section

ICD-10 code

T81.4

ICD-10 code description

عفونت بدنیاال سزارین

Primary outcomes

1

Description

Symptoms of infection

Timepoint

Before intervention, the data of these patients were recorded And followed up for 40 days after intervention and discharge And their information is recorded.

Method of measurement

Questionnaire to record patient demographic information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: They receive a dose of antibiotic after surgery.

Category

Diagnosis

2

Description

Intervention group 2: They receive three doses of antibiotics after surgery.

Category

Diagnosis

3

Description

Intervention group 3: They do not receive any antibiotics after surgery.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

sarem women hospital

Full name of responsible person

Dr. Mojgan Karamnia far

Street address

Phase 3- Ekbatan Town, Tehran, iran

City

Tehran

Province

Tehran

Postal code

1396956111

Phone

+98 21 4467 0883

Email

dr.karamnia@saremhospital.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sarem Fertility and Infertility Research Center

Full name of responsible person

Maryam Mahmoodinia Maymand

Street address

Phase 3- Ekbatan Town, Tehran, iran

City

Tehran

Province

Tehran

Postal code

1396956111

Phone

+98 21 4467 0883

Email

dr.karamnia@saremhospital.org

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sarem Fertility and Infertility Research Center

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Sarem Infertility Fertility Research Center

Full name of responsible person

Dr. Mojgan Karamnia far

Position

Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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City

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Tehran

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1396956111

Phone

+98 21 4467 0883

Email

dr.karamnia@saremhospital.org

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sarem Fertility and Infertility Research Center

Full name of responsible person

Dr. Mojgan Karamnia far

Position

Specialist

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sarem Fertility and Infertility Research Center

Full name of responsible person

Dr. Mojgan Karamnia far

Position

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Latest degree

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009844670883

Email

dr.karamnia@saremhospital.org

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available