

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of efficacy of prophylactic antibiotic prescribing before cesarean section and antibiotic administration after cord clamping on prevention of post-cesarean infection

Protocol summary

Study aim

Comparison of efficacy of prophylactic antibiotic prescribing before cesarean section and antibiotic administration after cord clamping on prevention of post-cesarean infection

Design

A clinical trial with a sample size of 180 patients with intervention and control groups, with parallel group design, triple blind, randomized, phase 3

Settings and conduct

This study will be conducted at Shahidan Mobinini Hospital in Sabzevar. People will be randomly divided into two groups; Follow up of mothers will be performed by the physician within the first 48 hours after cesarean section (during admission). In the absence of infection symptoms, patients will be discharged on day 2 and then will be investigated on day 7-10. They will inform us if they have any problem until the 14th day after the cesarean section. Blinding: The patient, the project manager and his assistant, and the design consultant are not aware of the contents of the prescribed drug packs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women who are referred for cesarean section according to indication. Non-inclusion criteria: taking antibiotics 24 hours before C/S, underlying illness, presence of Chorioamnionitis criteria, fever, use of immunosuppressive drugs.

Intervention groups

Intervention group: 90 pregnant women receiving antibiotics immediately after umbilical cord clamp and distilled water one hour before cesarean delivery. Control group: 90 pregnant women receiving antibiotics immediately after cesarean section and distilled water immediately after umbilical cord clamp.

Main outcome variables

Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190526043710N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **retrospective**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Zeinab Shahbazzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7773 4246

Email address

shahbazzadez90@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-14, 1398/03/24

Expected recruitment end date

2019-07-10, 1398/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of prophylactic antibiotic prescribing before cesarean section and antibiotic administration after cord clamping on prevention of post-cesarean infection

Public title

Comparison of efficacy of antibiotic before and after C/S to prevent post-cesarean infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women who undergo C/S due to midwifery indications or other reasons Providing informed consent

Exclusion criteria:

Having underlying diseases (DM, liver diseases, kidney diseases, suppressed immune sys) The presence of chorioamnionitis criteria (lochia, tenderness, fever) Fever (oral temperature above 38 degrees) Rupture of membranes more than 24 hours Immunosuppressive drugs use (corticosteroids and etc) Use of antibiotics 24 hours before cesarean section

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Random unit: Individual Randomization Tool: Random Number Tables How to create a random sequence: A random number table using www.randomization.com Hiding: Hiding in this study will be done by the central service and people who do not have any information about the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be treated by prescription drug packs (which are quite similar in appearance). Patient and executor are not aware of the contents of packages. Information gathering, patient assessment and completion of the forms will be carried out by the executor and her assistant who are not aware of the contents of packages. The data analysis will also be done by the statistician who is not aware of packages contents and only is aware of the grouping (group 1 or 2). Therefore, the study is a triple blinded study and the patient's arrival stage to the study, data collection and analysis, the contents of the

packs will not be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohidshahr Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.MEDSAB.REC.1398.015

Health conditions studied

1

Description of health condition studied

Comparison of efficacy of antibiotic prescribing before and after cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of post Cesarean infection

Timepoint

During the Hospitalization and 10 or 14 days after cesarean section

Method of measurement

Physical examination and judgment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 90 pregnant mothers eligible for inclusion in the study will be prescribed antibiotics (routinely: single dose Cefazolin 1 g in subjects weighing less than 80 kg - 2 g in subjects weighing 80 kg or more- 3 g in subjects With weight greater than 120 kg, and in the case of allergy to penicillin, combine therapy with Metronidazole 100 mg or 600 mg of Clindamycin with Gentamycin 1.5 mg / kg body weight) after clamping the umbilical cord and Distilled water one hour before making the cut (cesarean section).

Category

Prevention

2

Description

Control group: 90 pregnant mothers eligible for inclusion in the study will be taken antibiotics (routinely: single dose Cefazolin 1 g in subjects weighing less than 80 kg - 2 g in subjects weighing 80 kg or more- 3 g in subjects With a weight greater than 120 kg, and in the case of allergy to penicillin, combine therapy with Metronidazole 100 mg or 600 mg of Clindamycin with Gentamycin 1.5 mg / kg body weight) One hour before making the cut (cesarean section) and distilled water immediately after cord clamping.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Shahidan Mobini hospital

Full name of responsible person

Dr. Gholam Abbas Kafi

Street address

North Kashefi Ave.

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr.Fereshteh Ghorat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zeinab Shahbazzadeh

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available