Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of prophylaxis antibiotic before and during operation on maternal and neonatal outcomes in pregnant women candidate for elective cesarean section

Protocol summary

Study aim
Comparison of the effect of prophylaxis antibiotic before and during operation on maternal and neonatal outcomes in pregnant women candidate for elective cesarean section

Design
After explaining the purpose of the study and obtaining the informed consent, patients under cesarean section will be allocated as parallel into A (intervention) and B (control) groups. Sample size: 360 participate in the study with 180 patients in each group

Settings and conduct
The study is single-center and phase 3 trial. Randomization will be performed using random block sizes of 4.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age greater than 34 weeks Exclusion criteria: Antibiotic use in the past two weeks; The temperature greater than 38 at least 2 times at intervals of 6 hours in the axillary region during surgery; Sensitivity to cefazolin antibiotics

Intervention groups
Intervention group: Cefazolin 2 gr, 15-30 minutes before surgery Control group: Cefazolin 2 gr, 15-30 minutes after exit the placenta

Main outcome variables
Maternal outcomes: Endometritis; Wound infection; Urinary tract infections Neonatal outcomes: Apgar; Hypothermia; Tachypnea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180525039834N1**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**

Registration date
2018-06-10, 1397/03/20

Registrant information

Name
Hanise Akbarzade

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8842 1720

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akbarzade@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-21, 1397/03/31

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of prophylaxis antibiotic before and during operation on maternal and neonatal outcomes in pregnant women candidate for elective cesarean section

Public title

Effect of prophylaxis antibiotic before and during operation on maternal and neonatal outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age greater than 34 weeks

Exclusion criteria:

Antibiotic use in the past two weeks The temperature greater than 38 at least 2 times at intervals of 6 hours in the axillary region during surgery Sensitivity to cefazolin antibiotics

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **360**

Randomization (investigator's opinion)

Randomized

Randomization description

using random block sizes of 4

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Vice chancellor for research, Shahroud University of Medical Sciences

Street address

Hafte-Tir Square

City

Shahroud

Province

Semnan

Postal code

3613773955

Approval date

2016-01-11, 1394/10/21

Ethics committee reference number

IR.SHMU.REC.1394.169

Health conditions studied

1

Description of health condition studied

Elective cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Endometritis

Timepoint

Before surgery and 1 week and 2 weeks after surgery

Method of measurement

Clinical evaluation

2

Description

Wound infection

Timepoint

Before surgery and 1 week and 2 weeks after surgery

Method of measurement

Clinical evaluation

3

Description

Urinary tract infection

Timepoint

Before surgery and 1 week and 2 weeks after surgery

Method of measurement

Clinical evaluation

4

Description

Apgar Score

Timepoint

At birth

Method of measurement

Clinical evaluation

5

Description

Hypothermia

Timepoint

At birth

Method of measurement

Clinical evaluation

6

Description

Tachypnea

Timepoint

At birth

Method of measurement

Clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cefazolin 2 gr, 15-30 minutes before surgery

Category

Treatment - Drugs

2

Description

Control group: Cefazolin 2 gr, 15-30 minutes after exit the placenta

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar hospital

Full name of responsible person

Hanise Akbarzade

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22 bahman St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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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

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Hanise Akbarzade

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Hanise Akbarzade
Position
Medical Student
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Medical doctor
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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
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