

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of single dose cefazolin versus single dose cefazolin plus seven days cephalixin prophylactic therapy on postoperative infections and early neonatal complications after elective cesarean section

Protocol summary

Summary

To Compare administration of single dose cefazolin versus single dose cefazolin plus seven days cephalixin prophylactic therapy on the early neonatal complications in Bushehr Persian Gulf Martyrs Hospital during 2015-2016. Two hundred and four pregnant women who are going to be delivered by non emergency cesarean section will be randomly divided to intervention and control groups. Intervention group will receive single dose cefazolin and control group will receive single dose cefazolin and oral cephalixin for seven days. Inclusion criteria: gravid one women with normal BMI. Exclusion criteria: obese women, history of antibiotic consumption during one week prior to cesarean section, immunosuppression, neonate with meconium stained amniotic fluid, duration of operation more than 30 minutes, patients with comorbidities. Mothers and their neonates will be visited in the first 48 hours and one week after delivery. Fever, chills, cellulitis, discharge from incision site, uterine tenderness in mother and diarrhea, rash and oral candidiasis in neonates will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506084339N10**
Registration date: **2015-07-10, 1394/04/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

Name

Elham Rahmani

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77125265914

Email address

rahmani@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Bushehr University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-22, 1395/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of single dose cefazolin versus single dose cefazolin plus seven days cephalixin prophylactic therapy on postoperative infections and early neonatal complications after elective cesarean section

Public title

Effect of administration of cefazolin in cesarean delivery on maternal postoperative infections and early neonatal complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: primi gravid; normal BMI Exclusion criteria: Obese women; history of antibiotic consumption in one week prior to cesarean section; immunosuppression; history of corticosteroid consumption; neonates with meconium stained amniotic fluid; duration of operation more than 30 minutes; patients with comorbidity.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Vice chancellor of research, Bushehr University of Medical Sciences

Street address

Bahmani Campus, Bushehr University of Medical Sciences, Sabzabad Blvd.

City

Bushehr

Postal code

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

Bpums.rec.139

Health conditions studied

1

Description of health condition studied

Early neonatal complications (rash, diarrhea, oral candidiasis) and maternal infections after elective cesarean section

ICD-10 code

P83.9, P78

ICD-10 code description

Antibiotics associated rash, diarrhea and oral candidiasis in neonate and maternal genitourinary and surgical site infections

Primary outcomes

1

Description

Diarrhea, rash and oral candidiasis in neonate

Timepoint

During first 48 hours after delivery and one week postdelivery

Method of measurement

History and physical examination

Secondary outcomes

1

Description

Surgical site infection

Timepoint

During first 48 hours post delivery and one week post delivery

Method of measurement

History, physical examination

2

Description

Metritis

Timepoint

During first 48 hours post delivery and one week post delivery

Method of measurement

History, physical examination

3

Description

Urinary tract infection

Timepoint

During first 48 hours post delivery and one week post delivery

Method of measurement

History, physical examination, urinalysis and urine culture

4

Description

Breastfeeding satisfaction

Timepoint

During first 48 hours post delivery and one week post delivery

Method of measurement

History

Intervention groups

1

Description

Control group: administrating cefazolin 1gr IV after clamping umbilical cord plus oral cephalixin 500 mg QID for seven days to mothers.

Category

Treatment - Drugs

2

Description

Intervention group: administrating cefazolin 1gr IV to mothers after clamping umbilical cord.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf Martyrs Hospital

Full name of responsible person

Dr Elham Rahmani

Street address

Persian Gulf Martyrs Hospital, Borj square, Borj Blvd.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Bushehr University of Medical Sciences

Full name of responsible person

Dr Afshin Ostovar

Street address

Bahmani Campus, University of Medical Sciences, Sabzabad Blvd

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research, Bushehr University of Medical Sciences

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

Bushehr University of Medical Sciences

Full name of responsible person

Dr Elham Rahmani

Position

Associate professor

Other areas of specialty/work

Street address

Persian Gulf Hospital, Borj Blvd, Borj square

City

Bushehr

Postal code

Phone

+98 77 3345 5374

Fax

Email

rahmani@bpums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr University of medical Sciences

Full name of responsible person

Dr Elham Rahmani

Position

Associate professor

Other areas of specialty/work

Street address

Persian Gulf Martyrs Hospital, Borj Blvd, Borj Square

City

Bushehr

Postal code

Phone

+98 77 3345 5374

Fax

Email

rahmani@bpums.ac.ir

Web page address

Person responsible for updating data

Contact

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