

# 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

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#### 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*