

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Compare effectiveness of broad spectrum antibiotic prophylaxy (Azitromycin + Keflin) with Keflin to prevent of post C/S infection in ER of Dr. Shariaty Hospital patient since 2011 July till 2012 August.

Protocol summary

Summary

Comparing the efficacy of prophylactic first- generation cephalosporin alone, with a first- generation cephalosporin plus azithromycin in reducing wound infection and endometritis after emergency cesarean section is the objective of this study. Inclusion: spontaneously labor or induced labor; rupture of membranes within 4 hour prior the termination; meconium passage before section and non-cephalic presentation. Exclusion: diabetes; multiple Pregnancy; history of Azitromycine or Erythromicine used in one last week; clinical finding about corioamniotitis; pulmonary edema; immunosupretion; Aids; patients who could not follow up after Cesarean section; preeclampsia; rapture of membrane more than 18 hour. This randomized controlled double blind clinical trial was done on 424 women over 14 year with gestational age more than 24 week who underwent emergency cesarean in Shariati Hospital in Bandar Abbas during 2011 July until 2012 August. Patients randomly divided to case and control group. Keflin 2 gram Intera Venus was prescribed 0.5 hour before surgery for both case and control groups. Case group also received azithromycin 1 gram oral 0.5 hour before surgery and control group received placebo. Patients were under observed till 1 month after surgery. Fever; open wound; endometritis and hospitalization were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041017211N1**
Registration date: **2014-05-05, 1393/02/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-05, 1393/02/15

Registrant information

Name

Maryam Iranfar

Name of organization / entity

HORMOZGAN University of medical Sciences (HUMS)

Country

Iran (Islamic Republic of)

Phone

+98 76 1333 3280

Email address

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare effectiveness of broad spectrum antibiotic prophylaxy (Azitromycin + Keflin) with Keflin to prevent of post C/S infection in ER of Dr. Shariaty Hospital patient since 2011 July till 2012 August.

Public title

Compare effectiveness of broad spectrum antibiotic

prophylaxy (Azitromycin + Keflin) with Keflin to prevent of post C/S infection in ER of Dr. Shariaty Hospital patient since 2011 July till 2012 August.

Purpose

Prevention

Inclusion/Exclusion criteria

The single most important risk factor for postpartum maternal infection is cesarean section. Women undergoing cesarean section have greater risk for infection and infectious morbidity compared with a vaginal birth. The objective of this study is to determine if extended spectrum prophylactic antibiotic treatment (cefazolin and azithromycin) reduces post-cesarean delivery infections. Inclusion: spontaneously labor or induced labor; rupture of membranes within 4 hour prior the termination; meconium passage before section and non-cephalic presentation. Exclusion: diabetes; multiple Pregnancy; patients who have contraindication to receive antibiotics; history of Azitromycine or Erythromicine used in one last week; clinical finding about corioamniotitis; pulmonary edema; immunosupretion; Aids; patients who could not follow up after Cesarean section; significant renal disease; preeclampsia; rapture of membrane more than 18 hour. This randomized controlled double blind clinical trial was done on 424 women over 14 year with gestational age more than 24 week who underwent non-elective cesarean in Shariati Hospital in Bandar Abbas during 2011 July until 2012 August. Patients randomly divided to case and control group. Keflin 2 gram Intera Venus was prescribed 0.5 hour before surgery for both case and control groups. Cases also received azithromycin 1 gram oral 0.5 hour before surgery. Patients were under observed till 1 month after surgery. Fever; open wound; endometritis and hospitalization were compared between two groups.

Age

From **14 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **424**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research and Technology
Hormozgan University of Medical Sciences, Bandar
Abbas,

Street address

East side of Shahid Mohammadi Hospital, Islamic
Republic of Iran BLVD

City

Bandar Abbas

Postal code

79145-3835

Approval date

2012-11-27, 1391/09/07

Ethics committee reference number

HEC-91-9-7

Health conditions studied

1

Description of health condition studied

To prevent post C/S infection

ICD-10 code

082.1

ICD-10 code description

Delivery by emergency caesarean section

Primary outcomes

1

Description

Fever

Timepoint

After intervention

Method of measurement

Thermometer in degrees Celsius

2

Description

Endometritis

Timepoint

After intervention

Method of measurement

Based on clinical symptoms such as fever, malodorous
discharge and uterine tenderness

3

Description

Wound infection

Timepoint

After intervention

Method of measurement

Number of open stitches

Secondary outcomes

1

Description

Length of stay

Timepoint

After intervention

Method of measurement

Days of hospitalization after surgery

Intervention groups

1

Description

Control Group received Cephalotin 2gr IV and placebo 1gr oral. These drugs were given only one dose before surgery. These groups of patients were admitted under full supervising 48 hours after surgery, and if fever was observed in each one, then she must be due to more time under supervising for differential diagnosis of the fever. After discharging, all of these patients were followed up for any sign of fever, endometritis and wound infection, for a month. Patients themselves, nurses and gynecologist those who followed up the postoperative of patients were unaware of the group and kind of drugs given to patients.

Category

Prevention

2

Description

Case group received Azithromycin and Cephalotin as a preoperative antibiotic prophylaxis. These drugs were given only one dose before surgery. These groups of patients were admitted under full supervising 48 hours after surgery, and if fever was observed in each one, then she must be due to more time under supervising for differential diagnosis of the fever. After discharging, all of these patients were followed up for any sign of fever, endometritis and wound infection, for a month. Patients themselves, nurses and gynecologist those who followed up the postoperative of patients were unaware of the group and kind of drugs given to patients.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. SHARIATI Specialized Hospital of Obstetrics and Gynecology

Full name of responsible person

Iranfar, Maryam (Obstetrics & Gynecology Resident)

Street address

North Intersection of Shahid Motahari avenue; Shahid

Nacer BLVD

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Azizi, Maryam

Street address

North Intersection of Shahid Motahari avenue; Shahid Nacer BLVD

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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

Hormozgan 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

Dr. Shariati Hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Maryam Abbassian

Position

Obstetrics & Gynecology Resident

Other areas of specialty/work

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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