

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of preoperative vaginal povidone iodine preparation on post cesarean infection

Protocol summary

Summary

We are going to investigate the effect of preoperative vaginal preparation with povidone-iodine as a preventive intervention against post cesarean endometritis and wound infection. The main inclusion criteria is undergoing non emergent cesarean delivery and exclusion criteria are history of sensitivity to betadine, chorio amnionitis, Active genital Herpes during pregnancy, and emergency cesarean section . 568 patients will be enrolled in this study. After signing informed written consent, each patient will be assigned to receive standard abdominal skin preparation with Povidone-Iodine or the standard abdominal preparation plus an additional 30 seconds vaginal scrub with Povidone-Iodine solution. All patients will receive a single dose of parental antibiotic prophylaxis with 1 gram cefazolin half an hour before operation and then for 24 hours. Only in intervention group vaginal preparation will be performed with sponge sticks saturated with povidone iodine solution. After discharging from hospital and complete a 6 week puerperal period their chart will be reviewed by physician for development of postoperative febrile morbidity, diagnosis of endometritis, and or wound infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706201233N1**
Registration date: **2009-02-09, 1387/11/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-02-09, 1387/11/21

Registrant information

Name

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Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research vice-chancellorship, Guilan University of Medical Science

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative vaginal povidone iodine preparation on post cesarean infection

Public title

The effect of preoperative vaginal povidone iodine preparation on post cesarean infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being candidate for non emergent cesarean delivery. Exclusion criteria: history of sensitivity to betadine, chorio amnionitis, Active genital Herpes

during pregnancy , any purulent discharge with pruritus or dysuria or malodor discharge during pregnancy, emergency cesarean section, fetal distress, vaginal bleeding due to placenta previa or placental abruption, no time for vaginal preparation.

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **284**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan university of medical science

Street address

namjo.street. Research vice chancellorship-Guilan university medical science

City

rasht

Postal code**Approval date**

2008-06-07, 1387/03/18

Ethics committee reference number

2007/132/3/پ

Health conditions studied**1****Description of health condition studied**

Post-cesarean infection

ICD-10 code

O86

ICD-10 code description

Other puerperal infections

Primary outcomes**1****Description**

Incidence of Fever

Timepoint

Before Cesarean section, and at the end of week 1 , 2, 3 , 4, 5, and 6 after operation

Method of measurement

Temperature>38 degree centigrade by oral thermometer

2**Description**

Uterine fundal tenderness

Timepoint

Before intervention,one month and after intervention 6 monthes

Method of measurement

Uterine palpation (Physical examination)

3**Description**

Incidence of wound infection

Timepoint

Before intervention,one month and after intervention 6 monthes

Method of measurement

Purulent discharge, pruritus

Secondary outcomes**1****Description**

Incidence of endometritis

Timepoint

Before Cesarean section, and at the end of week 1 , 2, 3 , 4, 5, and 6 after operation

Method of measurement

Physical examination

Intervention groups**1****Description**

One gr parenteral cephalosporin half an hour before operation

Category

Prevention

2**Description**

vaginal scrub with povidone-Iodine solution plus 1 gr parenteral cephalosporin half an hour before operation

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra treatment and educated center

Full name of responsible person

Maryam Asgharnia

Street address**City**

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research department

Full name of responsible person

Dr Sobhani

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Medical University, Namjo st.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for research department

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**

Guilan University of Medical Science, Rasht, Iran

Full name of responsible person

Maryam Asgharnia

Position

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Person responsible for scientific inquiries

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Reproductive Health Research Centre

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Position

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Seyede Fatemeh Dalil Hirati

Position

Obsterician

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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