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 povidine 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: 0
Registration date 2009-02-09, 1387/11/21

Registrant information
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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
**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/

**Health conditions studied**

1

**Description of health condition studied**

Post-cesarean infection

**ICD-10 code**

086

**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 months

**Method of measurement**

Uterine palpation (Physical examination)

3

**Description**

Incidence of wound infection

**Timepoint**

Before intervention, one month and after intervention 6 months

**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 cephazoline half an hour before operation

**Category**

Prevention

2

**Description**

Vaginal scrub with povidone-Iodine solution plus 1 gr parenteral cephazoline 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.
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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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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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