Clinical Trial Protocol
Iranian Registry of Clinical Trials
28 Apr 2020

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

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

Registrant information
Name
Maryam Asgharnia
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13 1322 5624
Email address
asgharnia@gums.ac.ir

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
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

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

Recruitment centers

1

Recruitment center
- Al-Zahra treatment and educated center

Full name of responsible person
- Maryam Asgharnia

Street address
- Rasht

Category
- Prevention
Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research department
Full name of responsible person
Dr Sobhani
Street address
Medical University, Namjo st.
City
Rasht
Grant name
Vice-chancellor for research department
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
Name of organization / entity
Guilan University of Medical Science, Rasht, Iran
Full name of responsible person
Maryam Asgharnia
Position
Associate professor of Guilan University of Medical Sciences
Other areas of specialty/work
Street address
Al-Zahra hospital, Namjo st.
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
+98 13 1322 8724
Email
Asgharnia@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Reproductive Health Research Centre
Full name of responsible person
Maryam Asgharnia
Position
Associated professor Guilan university of medical science
Other areas of specialty/work
Street address
Reproductive Health Research Centre, Al-Zahra hospital. Namjo st.
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
Asgharnia@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Reproductive Health Research Centre, Al-Zahra Hospital
Full name of responsible person
Seyede Fatemeh Dalil Hirati
Position
Obstetrician
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 13 1322 5624
Fax
Email
fatemehdalil@yahoo.com
Web page address

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