

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of vaginal preparation with povidone iodine on post cesarean infection in women admitted to hospital

Protocol summary

Summary

According to prevalence and complication of post cesarean infection, this study is done to determine the effectiveness of preoperative vaginal preparation an antiseptic solution to reduce post caesarean infectious morbidity and endometritis. This randomized clinical trial study is conducted on 400 patients referred to Rouhani hospital for elective cesarean section since 2013 to 2014. For case group, the vaginal washing before stomach washing is performed with two gauzes impregnated with povidone iodine 10%. Each gauze is rotated 360-degree in all parts of the vagina, especially in the fornixes, so that the washing process lasted 30 seconds. In both groups, the abdomen washing is done with povidone iodine 10% and 3 gauzes. The total duration of belly washing last for five minutes. The control group is only received the abdomen wash with povidone iodine. In all patients after clamping the umbilical cord, 2 g of intravenous Cefazolin is injected. All of Patients after 24 hours after surgery giving antibiotic. Information on the second 24 hours after surgery for the fever, uterine tenderness, foul-smelling and tachycardia is done. One week after discharge and after 6 weeks again they were examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061425292N6**
Registration date: **2016-06-27, 1395/04/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Sedigheh Smaeilzadeh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8301

Email address

crdu.rohan@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor research , Babol university of medical science

Expected recruitment start date

2014-03-31, 1393/01/11

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vaginal preparation with povidone iodine on post cesarean infection in women admitted to hospital

Public title

vaginal preparation with povidone iodine on post cesarean infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Elective cesarean section; Singleton pregnancy; Term pregnancy. Exclusion criteria: Patients with severe anemia (hematocrit less than 30%);

Diabetes; Recent use of antibiotics or cortisones; Twins or more pregnancy; Morbid obesity (over 114 kg); Along with premature rupture of membrane; Labor induction; Amniotic fluid bloody and meconial intraoperative.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 400

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

Ethics Committee of Babol university of medical science

Street address

Ganj Afrouz

City

Babol

Postal code

Approval date

2014-03-01, 1392/12/10

Ethics committee reference number

MUBABOL.REC.1392.10

Health conditions studied

1

Description of health condition studied

Infection after surgery

ICD-10 code

N 74

ICD-10 code description

N74.8

Primary outcomes

1

Description

Fever, Uterine tenderness, Tachycardia, Foul-smelling lochia

Timepoint

24 hours after surgery, After 1 week, After 6 weeks

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The vaginal washing before stomach washing is performed with two gauzes impregnated with povidone iodine 10%. Each gauze is rotated 360-degree in all parts of the vagina, especially in the fornixes, so that the washing process lasted 30 seconds and the abdomen washing is done with povidone iodine 10% and 3 gauzes .

Category

Prevention

2

Description

Control group: Only the abdomen washing is done with povidone iodine 10% and 3 gauzes .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani hospital

Full name of responsible person

Zeinab Zabihi

Street address

Ganjafrouz- Street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Babol university of medical science

Full name of responsible person

Mahmoud Babaie
Street address
Ganj Afrouz Street
City
Babol
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 of Babol university of medical science
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
Babol university of medical science
Full name of responsible person
Zeinab Zabihi
Position
MD
Other areas of specialty/work
Street address
Ganj Afrouz Street
City
Babol
Postal code
Phone
+98 11 3223 8301
Fax
Email
mojy_rad@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol university of medical science
Full name of responsible person

Azita Ghanbarpour
Position
Obstetrician and gynecologist
Other areas of specialty/work
Street address
Ganj Afrouz Street
City
Babol
Postal code
Phone
+98 11 3223 8301
Fax
Email
dr_ghanpour@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babol university of medical science
Full name of responsible person
Zeinab Zabihi
Position
MD
Other areas of specialty/work
Street address
Iran-Ganj Afrouz Street-Babol university of medical science
City
Babol
Postal code
Phone
+98 11 3223 8301
Fax
Email
mojy_rad@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