

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vaginal cleansing with betadine before cesarean delivery on postoperative infectious morbidity in women with premature rupture of the membranes

Protocol summary

Summary

The main goal of the study is: evaluating the effect of vaginal cleansing with betadine before cesarean delivery on postoperative infectious morbidity in women with premature rupture of the membranes. The specific goals of the study are to compare fever, endometritis, and infectious morbidity related to the surgical wound between the two group with and without cleansing with betadine. The use of the study is to use this method if it would be effective. 100 pregnant women candidate of non-emergent cesarean section with premature rupture of membrane are randomly divided into two equal intervention and control groups. All patients are undergone cesarean section with phanensteil and kerr incision. Then the follow up of the patients will be done weekly to two weeks after cesarean and all the study variables will be evaluated with each visit. The two groups will be identical about age parity, gravidity, the time from the beginning of ruptured membrane. In the beginning, the following person will be unaware of the groups of the patients. inclusion criteria: history of ruptured membrane; candidates of cesarean with phanenshteil incision; those who have no more than two vaginal examinations. exclusion criteria: allergy to betadine; chorioamnionitis; active genital herpes; emergency cesareans; more than two vaginal examinations; more than 12 hours past the ruptured membranes; more than 1.5 hours duration of the operation. After randomization of patients into two groups, in the interventional group, the vagina is rinsed with 10% betadine for 30 seconds just before cesarean. In the control group nothing is done. All the patients are given 1g cephazoline before cesarean and 6 hour later for prophylaxis. They are followed weakly for two weeks. All the variables including, age; parity; gravidity; the interval from the ruptured membrane; fever(temperature=or>38 degree, 24 hours after

delivery; endometritis(uterus tenderness with fever, requiring antibiotics; wound complications(including dehiscence, infection requiring antibiotics, debridement) will be evaluated with each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111055485N2**

Registration date: **2011-12-07, 1390/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-07, 1390/09/16

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 2879

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Women's Reproductive Health Research Center, Tabriz University of Medical sciences

Expected recruitment start date

2010-12-10, 1389/09/19
Expected recruitment end date
 2011-12-03, 1390/09/12
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effect of vaginal cleansing with betadine before cesarean delivery on postoperative infectious morbidity in women with premature rupture of the membranes

Public title
 The effect of vaginal cleansing with betadine before cesarean delivery on postoperative infections in premature rupture of the membranes

Purpose
 Prevention

Inclusion/Exclusion criteria
 inclusion criteria: history of ruptured membrane; candidates of cesarean with phanenshteil incision; those who have no more than two vaginal examinations.
 exclusion criteria: allergy to betadine; chorioamninitis; active genital herpes; emergency cesareans; more than two vaginal examinations; more than 12 hours past the ruptured membranes; more than 1.5 hours duration of the operation.

Age
 From **16 years** old to **48 years** old

Gender
 Female

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **350**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not 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 Tabriz University of Medical Sciences
Street address
 Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street
City
 Tabriz
Postal code
Approval date
 2011-07-12, 1390/04/21
Ethics committee reference number
 5/4/3152

Health conditions studied

1

Description of health condition studied
 fever

ICD-10 code
 O86.0, O86

ICD-10 code description
 Infection of obstetric surgical wound , Infected: * caesarean section wound; Other infection of genital tract following delivery

Primary outcomes

1

Description
 fever
Timepoint
 before the operation, and 24 hours, one and two week after the operation
Method of measurement
 sublingual thermometer

2

Description
 endometritis
Timepoint
 the end of first and second week
Method of measurement
 physical examination

3

Description
 wound related complications
Timepoint
 the end of first and second week
Method of measurement
 physical examination

Secondary outcomes

1

Description
 infectious complication of the newborn

Timepoint

one day after and one and two weeks after cesarean

Method of measurement

diagnosis of neonatologists registered

2

Description

allergy to betadine

Timepoint

the day after cesarean

Method of measurement

the day after cesarean

Intervention groups

1

Description

In the intervention group, before scrubbing, the vagina will be rinsed with 10% betadine, with a sterile gloved hand.

Category

Prevention

2

Description

In the control group, the cleansing of the vagina will not be done.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra and Talegani Hospital

Full name of responsible person

Nazli Navali

Street address

Talegani Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Women's Reproductive Health Research Center, Tabriz University of Medi

Full name of responsible person

dr.Elahe Saheb Olad Madarec

Street address

Artesh street

City

Tabriz

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, Women's Reproductive Health Research Center, Tabriz University of Medi

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**

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

assistant professor/bord certificate of obstetrics and gynecology

Other areas of specialty/work**Street address**

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Person responsible for updating data

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