

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Preoperative vaginal preparation with Povidone -Iodinand the risk of post cesarean Endometritis

Protocol summary

Summary

In this randomized clinical trial 526 women undergoing cesarean delivery in university hospital in Mashhad (Iran) will be evaluated. Participants including 526 women undergoing cesarean delivery and nit having: preterm pregnancy, (GA<37), placenta previa, severe anemia (Hct<30), chorio aminoitis, Meconium Amniotic Fluid, Obesity (weight more than>114Kg), Multi fetal gestation, arrest in descending in station ≥ 0 and prolonged premature rupture of membranes (>18h). Intervention: subjects will receive either standard abdominal scrub alone or abdominal scrub with an additional vaginal preparation with povidone -iodine solution. All subjects receives prophylactic antibiotic after clamping the cord. Main Outcome measures (variables) are: each subject's postoperative course was reviewed for development of endometritis (fever and uterine tenderness after exclusion of other causes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105146467N1**

Registration date: **2011-06-18, 1390/03/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-18, 1390/03/28

Registrant information

Name

Nayerreh Ghomian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2631

Email address

ghomiann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-01-01, 1386/10/11

Expected recruitment end date

2009-01-01, 1387/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preoperative vaginal preparation with Povidone
-Iodinand the risk of post cesarean Endometritis

Public title

Relationship between vaginal preparation with Povidone
-Iodinand and Endometritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women who are candidate for cesarean section
Exclusion criteria: Preterm pregnancy; gestational age<37 weeks; placenta previa; severe anemia (Hct<30); chorioaminoitis; diabetes mellitus; Meconium Amniotic Fluid; Obesity (weight>114Kg); Multifetal gestation; prolonged induction(>10hours); arrest in descending in station ≥ 0 and prolonged premature rupture of membranes(>18hours)

Age

From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **526**

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
Faculty of Medicine

Street address
Vakil abad blv.

City
Mashhad

Postal code

Approval date
2007-04-22, 1386/02/02

Ethics committee reference number
2036-T

Health conditions studied

1

Description of health condition studied
Endometritis

ICD-10 code
n71.9

ICD-10 code description
Inflammatory disease of uterus except cervix

Primary outcomes

1

Description
Body temperature

Timepoint
Daily

Method of measurement

Thermometer

Secondary outcomes

1

Description
Endometritis

Timepoint
Daily

Method of measurement
Fever and uterine tenderness after exclusion of other causes

Intervention groups

1

Description
Intervention group: vaginal irrigation with povidone-iodine plus abdominal irrigation plus 2 gr cefazoline IV after clamping the cord

Category
Treatment - Drugs

2

Description
Control group: abdominal irrigation with povidone-iodine plus 2 gr cefazoline IV after clamping the cord

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza and Omolbanin hospitals

Full name of responsible person
Dr.Nayereh Ghomian

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashahad University of Medical Sciences

Full name of responsible person
Dr. Jalil Tavakol Afshari

Street address
Ghoreyshi

City
Mashhad

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, Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Nayereh Ghomian

Position

Associated Professor

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

Imam Reza Hospital

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Gynecologist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Nayereh Ghomian

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City

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Postal code**Phone**

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Fax**Email****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