Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of sub-lingual misoprostol and intravenous oxytocin in controlling of hemorrhage after cesarean section.

Protocol summary

Summary

Objectives: The aim of this study is to compare sub-lingual misoprostol and IV Oxytocin in reducing bleeding and its complications after caesarean section. Design: This study designs as a not blinded clinical trial. Setting and conduct: All subjects will randomly divide in two groups (50 patients in each group) and therapeutic interventions perform. Participants including major eligibility criteria: Participants include pregnant women who candidate for elective cesarean section. Inclusion criteria are singleton pregnant women, candidate for elective cesarean delivery and Gravid 1, 2 (maximum one section). Exclusion criteria are preeclampsia (high blood pressure and protein in the urine); cardiovascular diseases; asthma; uterine rupture; uterine leiomyoma or a women with a history of excessive bleeding after childbirth. Intervention: First group will receive 60 IU oxytocin intravenously (30 units during operation and 30 units during 12 hours after surgery) and second group 800 micrograms of misoprostol sublingual at the opening time of peritoneum. Blood pressure, heart rate and uterine tone will measure immediately after caesarean section and then each 30 minutes to one hour. HCT will be measured on arrival of patient to ward and 24 hours after it. One hour after cesarean section occurrence of side effects (nausea, chills, fever, hypotension, and tachycardia) will be evaluated and recorded. Main outcome measures (variables): The main outcome variable includes hematocrit values.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080514275N1**
Registration date: **2014-03-08, 1392/12/17**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-03-08, 1392/12/17

Registrant information

Name
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Semnan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sub-lingual misoprostol and intravenous oxytocin in controlling of hemorrhage after cesarean section.

Public title

Effect of misoprostol and oxytocin in controlling of hemorrhage after cesarean

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: singleton pregnant women; elective cesarean delivery; Gravid 1, 2 (maximum one section)
Exclusion criteria: Patients with preeclampsia (high blood pressure and protein in the urine); diseases cardiovascular diseases; asthma; uterine rupture; uterine leiomyoma or a women with a history of excessive bleeding after childbirth.
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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 Semnan University of Medical Sciences
Street address
Central Department, Semnan University of Medical Sicenses, Basidj Boulevard
City
Semnan
Postal code
Approval date
2013-09-01, 1392/06/10
Ethics committee reference number
92/16/6900

Health conditions studied

1

Description of health condition studied
Postpartum hemorrhage
ICD-10 code
072
ICD-10 code description
Postpartum haemorrhage

Primary outcomes

1

Description
Blood pressure, Heart rate, Shivering, Fever, Nausea and Uterian tone
Timepoint
Each 30 minutes up to 1 hour
Method of measurement
Clinical Assessment

Secondary outcomes

1

Description
Hematocrite
Timepoint
Before and 24 hours after intervention
Method of measurement
Laboratory value

Intervention groups

1

Description
First group will receive 60 IU oxytocin intravenously (30 units during operation and 30 units during 12 hours after surgery).
Category
Prevention

2

Description
Second group will receive 800 micrograms of misoprostol sublingual at the opening time of peritoneum.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al Momenin Hospital
Full name of responsible person
Dr. Neda Mirjan
Street address
Amir Al Momenin Hospital, Imam Hussein Square
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Sciences
Full name of responsible person
Raheb Ghorbani Ph.D
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Central Department of Semnan University of Medical Sciences, Basidj Boulevard
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Semnan
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 Semnan 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

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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