

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

Nahid Rahbar

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1446 0088

Email address

rahbar.nahid@sem-ums.ac.ir

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 Sciences, 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

Street address

Central Department of Semnan University of Medical Sciences, Basidj Boulevard

City

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

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Neda Mirjan

Position

Gynecology Resident

Other areas of specialty/work

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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