

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Sublingual Misoprostol to Reduce Blood Loss in Cesarean Delivery

#### Protocol summary

##### Summary

The aim of this study is to investigate the efficacy of sublingual misoprostol to reduce blood loss in cesarean delivery. In this randomized control trail, 90 pregnant women who are at risk of post partum hemorrhage will be divided into two groups, first group will receive sublingual misoprostol (400 microgram) and oxytocin and the control group will receive oxytocin. Hemoglobin and need for additional uterotonic during operation will be compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041125648N3**

Registration date: **2016-04-26, 1395/02/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-26, 1395/02/07

##### Registrant information

###### Name

Masoumeh Mirteimori

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 113 0199

###### Email address

rahmanish3@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-03-30, 1395/01/11

##### Expected recruitment end date

2016-05-01, 1395/02/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Sublingual Misoprostol to Reduce Blood Loss in Cesarean Delivery

##### Public title

Sublingual Misoprostol to Reduce Blood Loss in Cesarean Delivery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria are: any of post partum hemorrhage risk factors in term pregnancies like uterine over distention (macrosomia or multiple pregnancies); arrested descent labor; prolonged induction. Exclusion criteria are: coagulopathies; anemia; adhesion bands,; organ damage during surgery (intestine; colon; Bladder; etc); allergy for prostaglandins, abnormal placenta; need for extended surgery incision and underlying diseases (diabetes mellitus; hypertension; ischemic heart disease; etc).

##### Age

No age limit

##### Gender

Female

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **90**

##### 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 Mashhad University of Medical Sciences  
**Street address**  
Qoreishi Building, Daneshgah Street, Mashhad  
University of Medical Sciences, Mashhad, Iran  
Mashhad  
**City**  
Mashhad  
**Postal code**  
1234567  
**Approval date**  
2010-09-23, 1389/07/01  
**Ethics committee reference number**  
IR.MUMS.fm.REC.1394.354

## Health conditions studied

### 1

**Description of health condition studied**  
Cesarean Section  
**ICD-10 code**  
O82  
**ICD-10 code description**  
Single delivery by cesarean section

## Primary outcomes

### 1

**Description**  
Serum Hemoglobin  
**Timepoint**  
Before/ after surgery  
**Method of measurement**  
Laboratory

### 2

**Description**  
Need for additional uterotonic usage

**Timepoint**  
During surgery  
**Method of measurement**  
Clinical

## Secondary outcomes

### 1

**Description**  
Hospital stay duration  
**Timepoint**  
N/A  
**Method of measurement**  
Duration between admission and discharge

## Intervention groups

### 1

**Description**  
400 microgram Sublingual Misoprostol and oxytocin  
**Category**  
Treatment - Drugs

### 2

**Description**  
Oxytocin  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Ommol Banin Hospital  
**Full name of responsible person**  
Masoumeh Mirteimouri  
**Street address**  
Ayatollah Behjat Avenue, Ayatollah Behjat 16th,  
Mashhad, Iran  
**City**  
Mashhad

### 2

**Recruitment center**  
**Name of recruitment center**  
Ghaem Educational, Research and Treatment Center  
**Full name of responsible person**  
Masoumeh Mirteimouri  
**Street address**  
Ghaem Hospital, Dr. Shariati Square, beginning of  
Ahmadabad Avenue,  
**City**  
Mashhad

**3**

**Recruitment center**

**Name of recruitment center**

Imam Reza Educational, Research and Treatment Center

**Full name of responsible person**

Masoumeh Mirteimouri

**Street address**

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

**City**

Mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research of Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Qoreishi Building, Daneshgah Street, Vice Chancellor for Research of Mashhad University of Medical Sciences, Mashhad, Iran

**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 of 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**

Masoumeh Mirteimouri

**Position**

Gynecologist/ Assistant professor

**Other areas of specialty/work**

**Street address**

Ayatollah Behjat Avenue, Ayatollah Behjat 16th,

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+98 51 3623 1061

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rahmanish3@mums.ac.irsh79316@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Masoumeh Mirteimouri

**Position**

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**Other areas of specialty/work**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Masoumeh Mirteimouri

**Position**

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**Other areas of specialty/work**

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**City**

Mashhad

**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*