

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### A comparison of rectal and sublingual Misoprostol on decreases Post - Partum haemorrhage during cesarean section

#### Protocol summary

##### Study aim

Comparison of rectal and subcutaneous administration of misoprostol in bleeding during and after cesarean section

##### Design

Randomized clinical trial on two intervention groups of rectal misoprostol and sublingual misoprostol

##### Settings and conduct

This randomized double-blind clinical trial study will be performed on 80 pregnant women who referred to Shahid Sadoughi Hospital in Yazd for elective cesarean section. Mothers will be randomly divided into two groups. Immediately after the birth of the infant, 20 units of oxytocin will be infused in 500 ml ringer serum in both groups. In the first group 400 µg rectal misoprostol will be administered after spinal anesthesia and in the second group 400 µg sublingual misoprostol.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women (gestational age 37 and older), singleton pregnancy, and those who are candidates of cesarean section. Exclusion criteria: Fetal Distress, Macrosomia, Sensitivity to misoprostol, Previa, and Polyhydramnios

##### Intervention groups

This study included two intervention groups. The intervention group one consisted of 40 single-term pregnant women (gestational age 37 weeks and older) who were candidates for cesarean section and received rectal misoprostol. The intervention group two consisted of 40 pregnant women with similar conditions and received sublingual misoprostol. Both intervention groups received placebo during the intervention.

##### Main outcome variables

count of bleeding during and after delivery of cesarean section

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190204042614N1**  
Registration date: **2020-03-01, 1398/12/11**  
Registration timing: **retrospective**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

##### Registration date

2020-03-01, 1398/12/11

##### Registrant information

##### Name

Nooshin Hatamizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3822 4000

##### Email address

n.hatamizade@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-12-31, 1397/10/10

##### Actual recruitment start date

2018-05-01, 1397/02/11

##### Actual recruitment end date

2019-01-21, 1397/11/01

##### Trial completion date

2019-01-21, 1397/11/01

##### Scientific title

A comparison of rectal and sublingual Misoprostol on decreases Post -Partum haemorrhage during cesarean section

**Public title**

A comparison of rectal and sublingual Misoprostol on Post -Partum haemorrhage during cesarean section

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women who were candidates of Cesarean section

**Exclusion criteria:**

pregnancy induced hypertension twin pregnancy sensitivity to prostaglandin fetal distress

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

using convenient sampling method, the patients were selected. then, the patients were randomly assigned to two groups of rectal and sublingual using random number table.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Researcher and student

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences Yazd

**Street address**

Professor Hesabi Blvd, Shohadaye Gomnam Blvd, Medical Sciences Pardis

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173149

**Approval date**

2018-03-12, 1396/12/21

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1396.271

**Health conditions studied****1****Description of health condition studied**

bleeding during and after cesarean section

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Hemoglobin before and after surgery

**Timepoint**

6 hours after surgery

**Method of measurement**

Cell counter machine

**2****Description**

Hematocrit before and after surgery

**Timepoint**

6 hours after surgery

**Method of measurement**

Cell counter machine

**Secondary outcomes****1****Description**

Blood pressure

**Timepoint**

Every 5 minutes during surgery, every 15 minutes in recovery

**Method of measurement**

Device monitoring

**2****Description**

Heart beat

**Timepoint**

Every 5 minutes during surgery, every 15 minutes in recovery

**Method of measurement**

Device monitoring

**Intervention groups**

## 1

### Description

Intervention group: Rectal misoprostol is prescribed at a dose of 400 µg after spinal anesthesia. Placebo is also prescribed with rectal misoprostol.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Intervention group: sublingual misoprostol is prescribed at a dose of 400 µg after spinal anesthesia. Placebo is also prescribed with rectal misoprostol.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi Hospital in Yazd

##### Full name of responsible person

Nooshin hatamizadeh

##### Street address

Shahid Qandi Boulevard, Avicenna Street, Yazd  
Shahid Sadoughi Hospital

##### City

Yazd

##### Province

Yazd

##### Postal code

8915887857

##### Phone

+98 35 3822 4000

##### Fax

+98 35 3822 4100

##### Email

sadoughi\_hospital@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Nooshin Hatamizadeh

##### Street address

Bahonar Square, Shahid Sadoughi University of  
Medical Sciences

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Fax

+98 35 3725 4750

##### Email

medschool@ssu.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Yazd University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Nooshin Hatamizadeh

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Shahid Qandi Boulevard, Avicenna Street, Yazd  
Shahid Sadoughi Hospital

##### City

Yazd

##### Province

Yazd

##### Postal code

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##### Phone

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##### Email

n\_hatamizadeh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Afsar sadat Tabatabaee

##### Position

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Shahid Ghani Blvd.-Shahid Sadoughi hospital in Yazd

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**Province**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Nooshin Hatamizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Shahid Ghani Blvd.-Shahid Sadoughi hospital in Yazd

**City**

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**Province**

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**Postal code**

8915887857

**Phone**

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**Email**

n.hatamizade@ssu.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available