

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of rectal misoprostol before and after cesarean section on the amount of bleeding after the surgery

#### Protocol summary

##### Study aim

Investigation the effect of rectal misoprostol before and after cesarean section on the amount of bleeding after the surgery

##### Design

In this study 120 pregnant women candidate for elective cesarean section will be included in the study and after inclusion will be non randomly assigned into tow groups; before surgery group and after surgery group.

##### Settings and conduct

In all patients, after inclusion in the study, the hemoglobin level will be measured. In the group receiving misoprostol before the study, this drug will be used rectally just before skin incision and in the group receiving misoprostol this drug will be used rectally just after the end of cesarean section and closing the abdomen wound. In both groups the number of bloody guazes and the amount of blood in suction set and also the hemoglobin level will be determined. At the end of the study the amount of blood loss and decline in hemoglobin level will be compared together.

##### Participants/Inclusion and exclusion criteria

Inclusion criterion: all the term pregnant women candidate for elective cesarean section Exclusion criteria: placenta previa; diabetes mellitus; active labor; using anti-coagulant drugs; contraindication for using misoprostol.

##### Intervention groups

A group receiving misoprostal before cesarean: will receive one rectal misoprostol suppository just before cesarean section. A group receiving misoprostal after cesarean:will receive one rectal misoprostol suppository just after cesarean section.

##### Main outcome variables

Amount of blood loss Amount hemoglobin level decline

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180107038254N1**  
Registration date: **2018-02-05, 1396/11/16**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-05, 1396/11/16**

Update count: **0**

##### Registration date

2018-02-05, 1396/11/16

##### Registrant information

###### Name

Azam Sharafi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5715

###### Email address

azam.sharafi@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-21, 1396/11/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of rectal misoprostol before and after cesarean section on the amount of bleeding after the surgery

## Public title

The effect of misoprostol on the amount of bleeding in cesarean section

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

All full-term pregnant women candidate for elective cesarean section

### Exclusion criteria:

Placenta previa Diabetes mellitus Active labor Using anti-coagulant drugs

## Age

No age limit

## Gender

Female

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 120

## Randomization (investigator's opinion)

Not 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 Zahedan University of Medical Sciences

##### Street address

Ethics committee of Zahedan University of Medical Sciences

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9916789547

#### Approval date

2017-06-25, 1396/04/04

#### Ethics committee reference number

IR.ZAUMS.REC.1396. 29

## Health conditions studied

### 1

#### Description of health condition studied

Cesarean section

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Hemoglobin level

#### Timepoint

Before and after cesarean section

#### Method of measurement

Measured by laboratory

### 2

#### Description

Amount of blood loss

#### Timepoint

During cesarean section

#### Method of measurement

By measuring the amount of blood in suction set and the number of bloody gauzes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: in this group the patients will receive 2 200 mcg rectal misoprostol suppositories from Samisaz pharmaceutical company just before making the abdominal skin incision.

#### Category

Prevention

### 2

#### Description

Second Intervention group: in this group the patients will receive 2 200 mcg rectal misoprostol suppositories from Samisaz pharmaceutical company just after closing the abdominal wall.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital  
**Full name of responsible person**  
Aezam Sharafi  
**Street address**  
Khaliye Fars Blv, Zahedan  
**City**  
Zahedan  
**Province**  
Sistan-va-Balouchestan  
**Postal code**  
9916789547  
**Phone**  
+98 54 3329 5715  
**Email**  
aezam.sharafi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Hooshang Rafighdoost  
**Street address**  
Vice chancellor for research, Zahedan University of  
Medical Sciences campus, Jannat Blvd, Zahedan  
**City**  
Zahedan  
**Province**  
Sistan-va-Balouchestan  
**Postal code**  
9916789547  
**Phone**  
+98 54 3329 5715  
**Email**  
h.rafighdoost@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zahedan 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**  
Zahedan University of Medical Sciences

#### Full name of responsible person

Aezam Sharafi

#### Position

Gynecology resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Zahedan University of Medical Sciences and Health  
Services campus, Khaliye Fars Blv, Doctor Hesabi Sq,  
Zahedan

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9916789547

#### Phone

+98 54 3329 5715

#### Email

aezam.sharafi@yahoo.com

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Aezam Sharafi

#### Position

Gynecology resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Aezam Sharafi

#### Position

Gynecology resident

#### Latest degree

Medical doctor

**Other areas of specialty/work**

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**Email**

aezam.sharafi@yahoo.com

**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not 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