

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

8915887857

Phone

+98 35 3822 4000

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

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Email

afsar-tabata@yahoo.com

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

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

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