

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
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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
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Zahedan
Province
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+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,
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City

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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

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Email

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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