

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Efficacy of Rectal or Sub-lingual Misoprostol concomitant with Oxytocin for Prevention of Postpartum Hemorrhage in women with preeclampsia

Protocol summary

Study aim

Evaluation of the efficacy of prophylactic oral misoprostol in comparison with conventional treatment for reducing PPH (post-partum hemorrhage) in pre-eclampsia
Evaluation of the efficacy of prophylactic rectal misoprostol in comparison with conventional treatment for reducing PPH (post-partum hemorrhage) in pre-eclampsia
Evaluation of the efficacy of prophylactic oral and rectal misoprostol for reducing PPH (post-partum hemorrhage) in pre-eclampsia

Design

A randomized clinical trial with 2 intervention and 1 control groups, with parallel groups, double blinded, phase 3 on 126 patients, pocket shuffling was used for randomization.

Settings and conduct

The main researcher patients and data analyzer are blind to the study groups. After randomization with the shuffled pocket method, the patient enters the group at random. After spinal anesthesia with the same protocol and C-section, immediately after the umbilical cord clamp, the first group was injected with 400 micrograms of rectal misoprostol, the second group with 400 micrograms of rectal misoprostol. All groups including the control group only receive 30 U of Oxytocin according to the national protocol.

Participants/Inclusion and exclusion criteria

Inclusion: Age between 18 to 45 years Pregnant mothers with severe pre-eclampsia Hospitalization for C-section Gestational age over 35 weeks A maximum of 2 previous cesarean sections Complete removal of the placenta after cesarean section
Exclusion: Chronic hypertension Placental abnormality Complications or emergent condition during surgery High bleeding risk Indication for hysterectomy or TL

Intervention groups

Oral misoprostol Rectal misoprostol Control

Main outcome variables

Gauzes count for blood loss volume will be performed after the operation, 1 hour, 4 hours after surgery, and hemoglobin and hematocrit will be measured 24 hours after delivery.

General information

Reason for update

Only 126 patients were changed to 128 patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201022049108N1**

Registration date: **2020-11-05, 1399/08/15**

Registration timing: **prospective**

Last update: **2022-05-22, 1401/03/01**

Update count: **1**

Registration date

2020-11-05, 1399/08/15

Registrant information

Name

Mansoor Sadeghi Afkham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 3021

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Efficacy of Rectal or Sub-lingual Misoprostol concomitant with Oxytocin for Prevention of Postpartum Hemorrhage in women with preeclampsia

Public title
Evaluation of the effects of prophylactic misoprostol with oxytocin for postpartum hemorrhage in women with preeclampsia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
ALL pregnant mothers with severe pre-eclampsia who referred to the Shahi Kamali educational center in the study period Hospitalization for C-section Gestational age over 35 weeks Having a healthy and alive fetus Cephalic fetus A maximum of 2 previous cesarean sections Complete removal of the placenta after cesarean section The age of 18-45 years
Exclusion criteria:
Mothers with coagulation disorders History of maternal blood disorders Chronic hypertension Placental adhesion such as placenta previa and ecrta Placental abruption (overt and covert) Complications or emergency during surgery Eclampsia Mild pre-eclampsia Abnormal placenta History of uterine rupture High bleeding risk Indication for hysterectomy or TL

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Pocket shuffling, In this study for a total sample size of 128, the principle investigator write number 1 on 43 blank cards, number 2 on 43 blank cards, number 3 on 43 blank cards. Then, she place them in non-transparent pockets, then give all of them to another person that will shuffle them and put them in a box and give the box back to PI. For every patients included in the study, the PI picks up one card and assign the patient to one of the 3 groups based on the information on that card. The rest of the cards is then shuffled again and placed in a box to be used by another patient. This

continues until the last patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
First, dark envelopes were prepared for the number of total sample size, the inside of which was not visible in the light, and a paper that the name of groups was written on them were placed in them and placed in the operating room. The surgeon picks up an envelope and gives it to the PI. Based on the information in the envelope, the PI prescribes the medication for the patient. The patients and data analyzer will not know what kind of tratment were prescribed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iborz University of Medical Sciences

Street address

Kamali St.

City

Karaj

Province

Alborz

Postal code

3134877179

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.ABZUMS.REC.1399.186

Health conditions studied

1

Description of health condition studied

severe pre-eclampsia

ICD-10 code

O14.13

ICD-10 code description

Severe pre-eclampsia, third trimester

Primary outcomes

1

Description

Bleeding volume with gauze counting

Timepoint

Immediately, 1 hour, and 4 hours after C-section

Method of measurement

gauze counting

2**Description**

Hemoglobin and hematocrit changes

Timepoint

24 hours after C-section

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Oral misoprostol manufactured in Aboorehyan pharmacy CO, Iran, give to patients sublingually after C-section it is in combination with conventional treatment that is infusion of 30 IU (3 X ampule 10 IU/mL) of same company.

Category

Treatment - Drugs

2**Description**

Control group: Without Intervention: after C-section aconventional treatment that is infusion of 30 IU (3 X ampule 10 IU/mL) of Abooreyhan pharmacy CO. Iran. will give to patients.

Category

N/A

3**Description**

Intervention group: rectal misoprostol, Oral misoprostol manufactured in Aboorehyan pharmacy CO, iran, give to patients rectally after C-section it is in combination with conventional treatment that is infusion of 30 IU (3 X ampule 10 IU/mL) of same company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Kamali educational center

Full name of responsible person

Mansoorah Sadeghi Afkham

Street address

Shahid- Kamali educational center, Kamali Ave,
Shohad St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noori-Sepehr

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Mansoorah Sadeghi Afkham

Position

Resident of Obstetricians and Gynecologists

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mina Ataee

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mansoorah Sadeghi Afkham

Position

Resident

Latest degree

Medical doctor

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

When the data will become available and for how long

One year after finishing the study, data will be published and will be available in databases

To whom data/document is available

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

Under which criteria data/document could be used

Other researchers are permitted to include the results in their systematic reviews and metaanalysis

From where data/document is obtainable

Mina Ataee, Shahid Kamali Hospital, Alborz

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments