Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the Efficacy of Rectal or Sub-linguinal 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 conventiinal treatment for reducing PPH (post-partum hemorrhage) in pre-clampsia Evaluation of the efficacy of prophylactic rectal misoprostol in comparison with conventiinal treatment for reducing PPH (post-partum hemorrhage) in pre-clampsia Evaluation of the efficacy of prophylactic oral and rectal misoprostol for reducing PPH (post-partum hemorrhage) in pre-clampsia

Design

A randomized clinical trial with 2 intercention and 1 control groups, with parellel groups, double blinded, phase 3 on 126 patients, pockent 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 recieve 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 delievery.

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

Mansoore Sadeghi Afkham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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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-linguinal 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 blanck cards, number 2 on 43 blanck cards, number 3 on 43 blanck 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
Mansooreh 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
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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
Mansooreh Sadeghi Afkham
Position
Resident of Obstetricians and Gynecologists
Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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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 form 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 included 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