Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Effects of using misoprostol for cervical ripening in molar pregnancy, A Randomized Controlled Trial Study

Protocol summary

Study aim
Evaluation of the effects of misoprostol on pre-curettage preparation in molar pregnancy

Design
This study is a double blind clinical trial (parallel design) study. Samples will be taken from all the patients at Mahdieh and Imam Hossein Hospital In this study, random allocation of subjects to two intervention and treatment groups was performed using Balanced block randomization technique. Preparation of random assignment sequences of individuals and their enclosure in sealed envelopes, numbered with a 5-digit serial number, was performed by a third party who had no role in the design of the study. All envelopes (150 envelopes) were a random 5-digit serial number that was opened immediately after completion of baseline information and trials and assigned individuals to the intervention group (misoprostol) or control group.

Settings and conduct
This study is a double blind randomized clinical trial conducted in Mahdieh and Imam Hossein hospitals. In this double-blind study, the researcher and the clinical caregivers of the patient were unaware of the type of intervention and the preparation of random allocation sequences for individuals and their placement in sealed envelopes and Numbered with a 5-digit serial number, performed by a third party who did not participate in the study design.

Participants/Inclusion and exclusion criteria
Inclusion criteria include molar pregnancy. Exclusion criteria include a history of allergy to prostaglandins

Intervention groups
Intervention group (n = 75) (misoprostol recipient with a dose of 400 µg vaginal pre-suction curettage) and non-intervention group (n = 75) (curettage suction treatment and placebo prior vaginal delivery). They will be randomly selected from the studied samples.

Main outcome variables
Use of Misoprostol before Curettage in Molar Pregnancy for Cervical Preparation and its Softness to Reduce the Probability of Cervical Injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200216046519N1**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **retrospective**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date
2020-03-11, 1398/12/21

Registrant information

Name
Yekta Parsa

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2200 2365

Email address
yektaparsa@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
2018-03-21, 1397/01/01

Actual recruitment end date
2020-02-09, 1398/11/20

Trial completion date
2020-03-20, 1399/01/01

Scientific title
Effects of using misoprostol for cervical ripening in molar pregnancy, A Randomized Controlled Trial Study

Public title
Evaluation of misoprostol use for cervical preparation in molar pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with molar pregnancy who are candidates for termination of pregnancy

Exclusion criteria:
They are allergic to prostaglandins

Age
No age limit

Gender
Female

Phase
1

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **75**
Actual sample size reached: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects were divided into two groups of intervention and current treatment using Balanced block randomization technique Preparation of random assignment sequences of individuals and their enclosure in sealed envelopes, numbered with a 5-digit serial number, was performed by a third party who had no role in the design of the study. All envelopes (150 envelopes) were a random 5-digit serial number that was opened immediately after completion of baseline information and trials and assigned individuals to the intervention group (misoprostol) or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in this study and those in clinical care and the researcher were unaware of the type of intervention performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences, Ethics Committee for Biomedical Research

Street address
1, No. 1, Alley of Shade, Dashtyar St., East Sarvestan Street, Elahieh Ave.

City
Tehran

Province
Tehran

Postal code
1964713453

Approval date
2019-09-01, 1398/06/10

Ethics committee reference number
IR.SBMU.MSP.REC.1398.530

Health conditions studied

1

Description of health condition studied
Molar Pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Age of a small and independent variable - Gestational age of a small and independent variable - Parity of a small and independent variable - Uterine size of a small and independent variable - Bleeding during and after K. Quantitative and dependent variable drainage - Long-term variable and dependent variable of operation Quantitative and dependent variables of dilators

Timepoint
.

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pregnant mothers who received corticosteroid misoprostol at a dose of 400 microgram before suction

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahdieh Hospital

Full name of responsible person
yekta Parsa

Street address
Fadayian Eslam St, Shoush Square, Tehran

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Tehran

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1964713453

Phone
+98 21 5506 2654

Email
yektaparsa@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
yekta parsa

Street address
1, No. 1, Alley of Shade, Dashtyar St., East Sarvestan Street, Elahieh Ave.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
yekta parsa

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Position
resident
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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
Due to the rights of the participants
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available