

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of outpatient sublingual misoprostol 25 µg and oral misoprostol 50 µg on reducing post-term pregnancy and induction success and evaluation of maternal and fetal outcomes: a double-blind clinical trial

Protocol summary

Study aim

Determining the effect of outpatient misoprostol on cervical preparation and reduction of post-term pregnancy and delivery induction success

Design

In this double-blind clinical trial study, the sample size of patients was 70 pregnant women in each group (group A, B). Participants are selected from pregnant mothers who visit the midwifery clinic of Umm al-Banin and Imam Reza and Ghaem hospitals.

Settings and conduct

The midwifery clinic of Umm al-Banin and Imam Reza and Ghaem hospitals

Participants/Inclusion and exclusion criteria

Inclusion criteria included gestational age 40 weeks (based on first trimester ultrasound) and gravid primordia and monocyotogenesis, cephalic presentation, normal amniotic fluid (AFI greater than or equal to 5 cm), no history of medical and midwifery and Bishab Score is less than 8 and the mother is between 18 and 40 years old, with no uterine contractions.

Intervention groups

A group of patients taking Misoprostol 25 mg sublingual tablets and a group of Misoprostol tablets 50 micrograms oral will be given at a specific time of pregnancy.

Main outcome variables

Duration of Cervical Preparation to Delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045653N1**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

Registrant information

Name

sara partanezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 8409

Email address

partans941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-04, 1398/09/13

Expected recruitment end date

2020-12-03, 1399/09/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of outpatient sublingual misoprostol 25 µg and oral misoprostol 50 µg on reducing post-term pregnancy and induction success and evaluation of maternal and fetal outcomes: a double-blind clinical trial

Public title

sublingual misoprostol 25 µg and oral misoprostol 50 µg

on reducing post-term pregnancy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Maximum gestational age of 40 weeks pregnant women
Prime Grave Single pregnancy Cephalic display Having normal amniotic fluid (AFI greater than or equal to 5 cm)
Bishop Score less than 8 Maternal age between 18 and 40 years
Exclusion criteria:
History of medical and midwifery disease Diabetes
Preeclampsia History of stillbirth Opt out of the study
Improper use of medication

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
0

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly divided into treatment groups A and B using sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
researcher and Statistical analyzer are unaware of the dose of the drug being prescribed and the method of administration.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreyshi Department, Daneshgah Street.
City
Mashhad
Province
Razavi Khorasan

Postal code
9137913316
Approval date
2019-12-09, 1398/09/18
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.603

Health conditions studied

1

Description of health condition studied
termination of pregnancy
ICD-10 code
O04
ICD-10 code description
Medical abortion

Primary outcomes

1

Description
Duration of Cervical Preparation to Delivery
Timepoint
After Intervention
Method of measurement
Time

Secondary outcomes

1

Description
Fetal heart monitoring
Timepoint
After intervention
Method of measurement
Cardiac monitoring device

Intervention groups

1

Description
Intervention group: Misoprostol tablets 25 micrograms sublingual
Category
Prevention

2

Description
Control group: Misoprostol 50 mg oral tablets
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Midwifery clinic of Umm al-Banin and Imam Reza and Ghaem hospitals

Full name of responsible person

Sedighe Auati

Street address

Ghaem Hospital, Department of Obstetrics and Gynecology, Taghi Abad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3840 0000

Email

ayati@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

University Street, Qureshi Building

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3840 2081

Email

ramresearch@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sara Partanezhad

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Ghaem Hospital, Taghi Abad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3801 2611

Email

Partans941@mums.ac.ir

Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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City

Mashhad

Province

Razavi Khorasan

Postal code

9176999311

Phone

+98 51 3801 2111

Email

Partans941@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sara Partanezhad

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Department of Obstetrics and Gynecology, Ghaem
Hospital, Taghi Abad Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9176999311

Phone
+98 51 3801 2611

Email
Partans941@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Results

When the data will become available and for how long

After the project is over

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific use

From where data/document is obtainable

Request Partans941@mums.ac.ir by email

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

Provided by email

Comments