

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Determining the effect of outpatient vaginal administration of misoprostol to reduce the rate of postpartum pregnancy and successful induction of labor

#### Protocol summary

##### Study aim

Determine the effect of outpatient misoprostol administration on postmenopausal pregnancy and induction success

##### Design

Randomized clinical trial.

##### Settings and conduct

In this study, 90 primigravida women, referring to the Ghaem Hospital are randomly assigned to the intervention and control groups. 25 micrograms of vaginal misoprostol is administered and membrane stripping will be performed in the intervention group. If necessary, the same intervention will be done at 40th week of gestational age and then every other day until the 41th week (up to a maximum of 5 doses of misoprostol). In the control group, the membrane stripping is done on the same days for pregnant women.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Single-strike pregnancy, primitive gravid, cephalic presentation, normal amniotic fluid (AFI greater than or equal to 5 cm), no history of medical and obstetric and metabolic diseases, Bishop score less than 8 / reactive nst / maternal age between 18 to 40 years / no contrindication for misoprostol / no bad history of midwifery, fetal death or infertility / lack of evidence for placenta previa or adhesion / without uterine scar / No evidence of macrosomia / No evidence of IUGR. Exit criteria: lack of patient referral / diagnosis of pre-eclampsia after including the study

##### Intervention groups

Mothers of intervention group receive 25 microgram of vaginal misoprostol and membrane stripping. Mothers of control group only receive membrane stripping.

##### Main outcome variables

Delivery rate before 41th week of gestational age/ admission time to 2nd stage interval/First administration to delivery interval/duration of stage 2/ additional

interventions/final route of delivery/gestational age at admission/maternal and fetal complications

#### General information

##### Reason for update

The primary version did not mention the secondary outcomes. In this edition, the secondary outcomes have also been completed.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180215038742N1**  
Registration date: **2018-04-09, 1397/01/20**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-24, 1400/08/02**

Update count: **2**

##### Registration date

2018-04-09, 1397/01/20

##### Registrant information

###### Name

Farnaz Hadavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3841 3007

###### Email address

hadavif951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-09, 1397/01/20

##### Expected recruitment end date

2018-07-22, 1397/04/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Determining the effect of outpatient vaginal administration of misoprostol to reduce the rate of postpartum pregnancy and successful induction of labor

**Public title**

Determine the effect of prescribing of misoprostol in reducing postpartum pregnancy and delivery success

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women with gestational age 39 weeks  
Primigravida Between 18 - 40 years old Single tone pregnancy Normal fetal heart rate Cephalic presentation (Vertex) AFI equal or more than 5 cm No history of medical or midwifery disorders Bishop score less than 8 Reactive NST Without uterine contractions

**Exclusion criteria:**

Macrosomia Sensitivity to PGs Uterin wall scar Preeclampsia or blood pressure more than 140/90 mmhg PROM Vaginal Bleeding IUGR fetus

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are assigned to intervention or control group, using a series of opaque envelopes prepared by using random numbers generated from [www.randomizer.org](http://www.randomizer.org).

**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 Mashhad University of Medical Sciences

**Street address**

Central organization of the University, Knowledge and Health Township, Fakouri Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2017-12-13, 1396/09/22

**Ethics committee reference number**

IR.MUMS.fm.REC.1396.550

**Health conditions studied****1****Description of health condition studied**

Post-term Pregnancy

**ICD-10 code**

O48.0

**ICD-10 code description**

Post-term pregnancy

**Primary outcomes****1****Description**

Delivery rate before 41th week of gestational age.

**Timepoint**

39th week, 40th week and then every other day.

**Method of measurement**

newborn birth

**Secondary outcomes****1****Description**

admission time to 2nd stage interval

**Timepoint**

Admission time and stage 2

**Method of measurement**

time interval (hour)

**2****Description**

First administration to delivery interval

**Timepoint**

39th week, delivery time

**Method of measurement**

time interval (hour)

### 3

**Description**

duration of stage 2

**Timepoint**

full dilatation , fetal delivery

**Method of measurement**

time interval (min)

### 4

**Description**

additional interventions

**Timepoint**

Delivery time

**Method of measurement**

additional doses of oxytocin and misoprostol

### 5

**Description**

final route of delivery

**Timepoint**

delivery time

**Method of measurement**

normal vaginal delivery or cesarian section duo to documents

### 6

**Description**

maternal complication

**Timepoint**

delivery time

**Method of measurement**

Any complication that has been registered in the case file for the mother

### 7

**Description**

apgar score

**Timepoint**

first and 5th minutes after delivery

**Method of measurement**

apgar score scale

### 8

**Description**

meconial staining

**Timepoint**

delivery time

**Method of measurement**

observation at delivery time

### 9

**Description**

gestational age at admission

**Timepoint**

Admission time

**Method of measurement**

gestational age according first trimester sonography

### 10

**Description**

bishop score at admission

**Timepoint**

admission time

**Method of measurement**

according to bishop score scale

### 11

**Description**

additional dose of misoprostol or oxytocin

**Timepoint**

admission to delivery

**Method of measurement**

calculating additional dose of misoprostol or oxytocin

## Intervention groups

### 1

**Description**

Intervention group: Vaginal misoprostol (25 micrograms) in pregnant women and membrane stripping

**Category**

Treatment - Drugs

### 2

**Description**

Control group: membrane stripping

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Quaem hospital

**Full name of responsible person**

Farnaz Hadavi

**Street address**

Dr. Ali Shariati Sq., Ahmadabad Ave.

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3840 0000

**Email**

farnazhadavi@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

University compound, Azadi sqr.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 8888

**Email**

med.faculty@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**

Farnaz Hadavi

**Position**

Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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hadavif951@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Sedighe Ayati

**Position**

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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farnaz Hadavi

**Position**

Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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hadavif951@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**

Not applicable  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Not applicable  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable  
**Title and more details about the data/document**  
All anonymous data are shareable.  
**When the data will become available and for how**

**long**  
One year after publication  
**To whom data/document is available**  
Academic researchers  
**Under which criteria data/document could be used**  
For meta-analysis studies  
**From where data/document is obtainable**  
Email address  
**What processes are involved for a request to access data/document**  
After email reception  
**Comments**