Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Singletone 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.
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 diatation , 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
apgaar 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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99199-91766
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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.
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Mashhad
Province
Razavi Khorasan
Postal code
9177948564
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+98 51 3882 8888
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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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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