

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The Comparison of Vaginal Misoprostol with buccal and sublingual Misoprostol in Labor Induction in Term Pregnancy

#### Protocol summary

##### Study aim

Comparison of the effect of misoprostol on vaginal, sublingual and buccal methods in induction of labor in term pregnancies. Comparison of cesarean section among three groups Comparison of the need for oxytocin in three groups Comparison of maternal complications among the three groups Comparison of fetal complications among the three groups

##### Design

Three parallel group, Randomised trial , without blinded

##### Settings and conduct

The study population of this study is women referred to Qazvin Kosar Hospital during the year 2018 who are randomly divided into 3 groups of Misoprostol buccal, sublingual and vaginal. The final sample size is about 100patients per group (300 patients). The data collection is based on the previous checklist. The data are analyzed using SPSS21 software and Kruskal-Wallis analysis, variance tests, mean, and standard deviation were used.

##### Participants/Inclusion and exclusion criteria

The present study will be conducted as a clinical trial. All patients referring to Kowsar Hospital, who had indications of delivery for maternal reasons, included criteria for entering the study, and if they don not have the criteria for exit, they would enter the study after completing the informed consent form. The age of the mother, the gestational age, the BMI of the mother, and the Bishop score in the first visit are recorded by the resident of the gynecologist. The gestational age is determined based on the last menstruation date confirmed by early ultrasonography. Patients are randomly divided into three groups based on randomized method.

##### Intervention groups

the first group, recieved vaginal misoprostol 25 mcg every 6 hours until24 hours, the second group received 50 mcg sublingual misoprostol every 6 hours until24 hours, and the third group received 50 mcg misoprostol buccal every 6 hours until24 hours for induction of labor

#### Main outcome variables

Choosing the best, least expensive, most effective, and least complicated therapies for induction of childbirth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180121038465N1**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

##### Registration date

2018-03-17, 1396/12/26

##### Registrant information

##### Name

Razieh Akbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3350 4866

##### Email address

raziehakbari9@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-14, 1396/12/23

##### Expected recruitment end date

2018-07-01, 1397/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The Comparison of Vaginal Misoprostol with buccal and sublingual Misoprostol in Labor Induction in Term Pregnancy

**Public title**  
The Comparison of Vaginal Misoprostol with buccal and sublingual Misoprostol in Labor Induction in Term Pregnancy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
single, bishop score  $\leq 4$ , cephalic presentation, NST reactive, parity  $\leq 2$ , gestational age more than 37 w, Amniotic fluid index  $\geq 5$

**Exclusion criteria:**  
maternal medical diseases breech presentation fetal anomaly

**Age**  
No age limit

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **300**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple randomization was performed in this research.

**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 Qazvin University of Medical Sciences  
**Street address**  
Kousar Hospital, Ayatollah Khamenei Ave, Qazvin  
**City**  
Qazvin

**Province**  
Qazvin  
**Postal code**  
13176- 34156

**Approval date**  
2018-03-13, 1396/12/22

**Ethics committee reference number**  
IR.qums.rec.1396.497

**Health conditions studied**

**1**  
**Description of health condition studied**  
induction of labour  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

**1**  
**Description**  
The effect of misoprostol in induction of labor  
**Timepoint**  
every 6h to 24h  
**Method of measurement**  
bishop score and time of delivery

**Secondary outcomes**

**1**  
**Description**  
the rate of Cesarean section  
**Timepoint**  
delivery  
**Method of measurement**  
cesarean/ NVD

**2**  
**Description**  
reason of cesarean  
**Timepoint**  
during delivery  
**Method of measurement**  
mecunium, FHR deceleration, No response to induction

**3**  
**Description**  
time to the active phase of labor  
**Timepoint**  
0-6-24 hr  
**Method of measurement**  
Bishop Score

**4**  
**Description**  
need for oxytocin

**Timepoint**

until delivery

**Method of measurement**

yes/no

**5****Description**

number of misoprostol doses

**Timepoint**

until delivery

**Method of measurement**

1-2-3

**6****Description**

fetal complications

**Timepoint**

until delivery

**Method of measurement**

abnormal pattern of fetal heart rate, meconium, Apgar score 1 and 5 postpartum, and admission to neonatal intensive care unit

**7****Description**

maternal complication

**Timepoint**

until delivery

**Method of measurement**

Fever, chills, nausea, vomiting, uterine tachysystole, uterine hyperstimulation

**Intervention groups****1****Description**

Intervention group: Recipient of 50 µg misoprostol by buccal method up to three doses in case of no onset of labor pain

**Category**

Treatment - Devices

**2****Description**

Intervention group: Recipient of 50 µg misoprostol by sublingual method up to three doses in case of no onset of labor pain

**Category**

Treatment - Devices

**3****Description**

Control group: Recipient of 25µg misoprostol by vaginal method up to three doses in case of no onset of labor pain

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kousar Hospital

**Full name of responsible person**

Razieh Akbari

**Street address**

Kousar Hospital, Shahid Taleghani Street, Kousar Alley

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**Postal code**

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**Phone**

+98 28 3323 6374

**Email**

raziehakbari9@gmail.com

**Web page address**<http://hoskosar.qums.ac.ir/Portal/Home/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Amir Peymani

**Street address**

Qazvin University of Medical Sciences, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

59811-34197

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+98 28 3333 6001

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apeymani@qums.ac.ir

**Web page address**<http://vcr.qums.ac.ir/portal/home/default.aspx?categoryid=c8d7bfff-95fd-4021-bfa1-6b2415a02d7c&rnd=44115.18399915726>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin 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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Razieh Akbari  
**Position**  
Gynecology Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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Qazvin- Kosar Hospital  
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## Person responsible for scientific inquiries

### Contact

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**Position**  
Gynecology Resident  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Razieh Akbari  
**Position**  
Gynecology Resident  
**Latest degree**  
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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

No more information

### 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