

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Aug 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

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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 ≤ 4 , cephalic presentation, NST reactive, parity ≤ 2 , gestational age more than 37 w, Amniotic fluid index ≥ 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

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Kousar Hospital, Shahid Taleghani Street, Kowsar Alley

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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

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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