Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 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, Ayatolah 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 responce 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, Kowsar Alley
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13176- 34156
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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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Qazvin
Province
Qazvin
Postal code
59811-34197
Phone
+98 28 3333 6001
Email
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

Gynocology Resident

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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Full name of responsible person

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Position

Gynocology Resident

Latest degree

Medical doctor

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Person responsible for updating data

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Position

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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