

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

comparative evaluation of the effect of vaginal misoprostol to vaginal misoprostol with nitroglycerine in cervix ripening in pregnant women at term referred to Kowsar hospital of Qazvin province

Protocol summary

Study aim

comparative evaluation of the effect of vaginal misoprostol to vaginal misoprostol with nitroglycerine in cervix ripening in pregnant women at term

Design

Randomized clinical trial, Parallel.

Settings and conduct

Participants of the study included 106 pregnant women aged more than 37 weeks who were admitted to Kosar Hospital and were randomly assigned to one of the two groups of single and double dose drugs (each group is 53 patients). For the single-dose group, misoprostol is given at a dose of 25 micrograms vaginal and for group two, misoprostol is given with a dose of 25 micrograms vaginal, with nitroglycerin 40 mg vaginal. Then, patients are evaluated for the purpose of cervical preparation.

Participants/Inclusion and exclusion criteria

Major entry criteria: Primigravida; Gestational age higher than 37 weeks; Bishop score more than 4 Major no- entry criteria: Surgery on the uterus or previous cesarean section; chronic hypertension and preeclampsia

Intervention groups

First intervention group: In the dual drug group, misoprostol is given at a dose of 25 micro grams vaginal with nitroglycerin 40 mg vaginal and after 6 hours, the cervix is examined for Bishop Score, and in the case of inappropriate cervix, 25 micrograms of the next misoprostol is administered up to a maximum of 4 doses. Second intervention group: In the single dose group, misoprostol is given with a dose of 25 micrograms of vaginal and after 6 hours, the cervix is examined for Bishop Score in case of inappropriate cervix, 25 micro grams of misoprostol is administered up to a maximum of 4 doses.

Main outcome variables

The duration of cervical ripening until delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120428009576N4**

Registration date: **2020-02-03, 1398/11/14**

Registration timing: **retrospective**

Last update: **2020-02-03, 1398/11/14**

Update count: **0**

Registration date

2020-02-03, 1398/11/14

Registrant information

Name

Ezzatsadat Haji seyed javadi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3223 6374

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative evaluation of the effect of vaginal misoprostol to vaginal misoprostol with nitroglycerine in cervix ripening in pregnant women at term referred to Kowsar hospital of Qazvin province

Public title

comparative evaluation of the effect of misoprostol vaginal suppository to vaginal misoprostol with nitroglycerine in ripening of cervix in term pregnancy referred to kowsar hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravida Gestational age ≥ 37 week Bishop score ≤ 4 Cephalic presentation Reactive NST Viable fetus Estimated weight before 4 kilogram Amniotic fluid > 5 Singleton

Exclusion criteria:

Surgery on the uterus or previous cesarean section chronic hypertension and preeclampsia uterine contractions The presence of heart, kidney and liver disease rupture of membrane IUGR Suspected embryonic anomalies chorioamnionitis Fever above $38^{\circ}C$ polyhydramnios Pre-delivery hemorrhage fetal distress

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to randomized groups based on the demographic data and then divided into two groups. The paired numbers are then assigned to the misoprostol group and the individual numbers to the misoprostol group together with nitroglycerin. Then by moving one of the numbers, we move in a predetermined direction.

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

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.QUMS.REC.1397.035

Health conditions studied

1

Description of health condition studied

Ripening cervix

ICD-10 code

-

ICD-10 code description

Primary outcomes

1

Description

The duration of cervical ripening until delivery

Timepoint

6 and 12 hours

Method of measurement

Vaginal exam

Secondary outcomes

1

Description

Duration of taking the drug until the onset of the active phase of labor

Timepoint

every 2 hours

Method of measurement

Vaginal exam

2

Description

Duration of taking drug until delivery

Timepoint

every 2 hours

Method of measurement

Vaginal exam

3

Description

Duration of the first phase of labor

Timepoint

every 2 hours

Method of measurement

Vaginal exam

4

Description

Duration of the second phase of labor

Timepoint

every 1 hours

Method of measurement

Vaginal exam

5

Description

Reach to vaginal delivery

Timepoint

After delivery

Method of measurement

Date sheet

6

Description

Type of delivery

Timepoint

After delivery

Method of measurement

Date sheet

Intervention groups

1

Description

First intervention group: In the dual drug group, misoprostol is given at a dose of 25 micro grams vaginal with nitroglycerin 40 mg vaginal and after 6 hours, the cervix is examined for Bishop Score, and in the case of inappropriate cervix, 25 micrograms of the next misoprostol is administered up to a maximum of 4 doses.

Category

Treatment - Drugs

2

Description

Second intervention group: In the single dose group, misoprostol is given with a dose of 25 micrograms of vaginal and after 6 hours, the cervix is examined for Bishop Score in case of inappropriate cervix, 25 micro grams of misoprostol is administered up to a maximum of 4 doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Maryam Rafiee

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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
Maryam Rafiee
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information is the most commonly used questionnaire, which is a statistical analysis

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

Path analysis

From where data/document is obtainable

Dr Ezzatsadat Hajseyedjavadi

What processes are involved for a request to access data/document

The email will be submitted to the project promoter at the discretion of the information.

Comments