Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparative evaluation of the effect of vaginal misoprostol to vaginal misoprostol with nitroglycerine in cervix rippening 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 rippening 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 uteus 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)

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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 rippening 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 rippening of cervix in term pregnancy reffered 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 uteus or previous cesarean section chronic hypertension and preeclampsia uterine contractions The presence of heart, kidney and liver disease rapture of membrane IUGR Suspected embryonic anomalies chorioamnionitis Fever above 38 ° 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 fist 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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 Hajseyyedjavadi
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