Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison Of The Effect Of Misoprostol On Induction Of Labour In Term Pregnancy: Double Blind Randomized Clinical Trial

Protocol summary

Study aim
1) Comparison of the initiation induction interval and the time of onset of pain 2) Comparison of the duration of induction to delivery 3) Comparison of delivery type 4) Comparison of the complications of clinical and uterine medication 5) Comparison of fetal complications (heart rate and meconium excretion) 6) Comparison of neonatal outcomes (Apgar, asphyxia)

Design
Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct
The population of the study: The subjects were pregnant women with a maximum natural history of delivery (referring to Mehregan and Kosar hospitals of Qazvin province during the years 2019-2020, who are candidates for induction of labor).

Participants/Inclusion and exclusion criteria
single viable term, underweight cephalic AFI>5, nst active bishop<5, IUGR 1, diabetic, mild preeclampsia, coronic hypertention-PPROM-pstdate

Intervention groups
Each group is randomly assigned 50 micrograms of vaginal misoprostol with cervical or cisplatin mizoprostol with vaginal placenta or basal mesoprostol with vaginal placement, so that the investigator and the prescriber have no information about the placebo and the drug.

Main outcome variables
Increasing the probability of termination of pregnancy by the natural delivery method, along with the benefits of natural delivery, such as a full-blown infant, early and successful breastfeeding, beginning normal activity and feeding at one hour after delivery, and ...

General information

Reason for update

Acronym
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IRCT registration information
IRCT registration number: **IRCT20190415043278N1**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-27, 1398/03/06**
Update count: **0**

Registration date
2019-05-27, 1398/03/06

Registrant information

Name
mahtab dadashaliha

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3322 9304

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison Of The Effect Of Misoprostol On Induction Of Labour In Term Pregnancy: Double Blind Randomized Clinical Trial

Public title
Comparison Of The Effect Of Misoprostol On Induction Of Labour In Term Pregnancy: Double Blind Randomized Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single Viable Term Fetus, Gestational Age>=39 Week, Fetal Weight < 4 kg , Cephalic, AFI>5, Nst Active ,No Pelvic Stricture, Bishop Score <5 ,IUGR Grade 1, Mild Diabetic, Pre eclampsia, Chronic Hypertension ,PPROM, Post Date Pregnancy
Exclusion criteria:
IUGR Grade >1,Fetus Malformation , Previous Uterine Scar , Multi Parity >2 , OT>38 ,Chorioamnionitis , Olygo & Poly Hydramniotic ,Macrosomia , Nst Non Reactive ,History of a Mothers Seizure , Hypotension-Renal & Heart Diese, Gestational Age < 36 Week.
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Simply randomize to three equal groups using Random allocation (Software) in one of the following three groups: A: Fifty micrograms of vaginal misoprostol (Cytotec, Searle, England) and cervical placenta B: Fifty micrograms of cystic myosoprostol (Cytotec, Searle, England) and vaginal placenta C: Fifty micrograms of subcutaneous misoprostol (Cytotec, Searle, England) and vaginal placenta.
Blinding (investigator's opinion)
Double blinded
Blinding description
double blind a randomized clinical trial(patient and researcher)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qazvin University Of Medical Science
Street address
Navab Street
City
Qazvin
Province
Qazvin
Postal code
3491658875
Approval date
2019-03-13, 1397/12/22
Ethics committee reference number
IR.QUMS.REC.1397.409

Health conditions studied

1

Description of health condition studied
Reduce The Duration Of Induction To Delivery In Pregnant Mothers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comparison Of The InitiationI Induction Interval And The Time Of Onset Of Pain In The Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) In Qazvin
Timepoint
Admision in Labure
Method of measurement
Time

2

Description
Comparison Of The Duration Of Induction To Delivery In Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) In Qazvin
Timepoint
Admision in Labure
Method of measurement
Time

3

Description
3) Comparison Of Delivery Type In Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) In Qazvin
Timepoint
Admision in Labure

Method of measurement
NVD , C/S

4

Description
Comparison Of The Complications Of Clinical And Uterine Medication In Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) In Qazvin
Timepoint
Admision in Labure
Method of measurement
Tachycardia (presence Of 5 Or More Uterine Contractions In 10 minutes), Excessive Uterine Stimulation (Any Condition That Causes Abnormal Fetal Heart Rate), Uterine Hypertonia (Any Uterine Contraction Lasting More Than Two Minutes), Start Time Suitable Contractions Of Uterus, Interval Between Initiation Of Induction And Delivery, Type Of Delivery, Meconium Excretion, Fetal Death, Apgar Score In the First And Fifth Minutes, And The Need For NICU Neonates Due To Low Apgar Score And Side Effects Of The Drug. Digestive Complications Include Nausea, Vomiting, Diarrhea, Fever And Headache

5

Description
Comparison Of fetal Complications (Heart Rate And Meconium Excretion) In Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) in Qazvin
Timepoint
Admision in Labure
Method of measurement
Number Of Meconium Excretion, Fetal Death, Apgar Score In First And Fifth Minutes, And Need For NICU Neonates due to Low Apgar Score

6

Description
Comparison Of Neonatal Outcomes (Apgar, Asphyxia) In Three Groups Of Pregnant Mothers (Vaginal, Cervical, Sublingual) Referring To Maternity Hospitals (Mehregan, Kosar) In Qazvin
Timepoint
Admision in labure after birth
Method of measurement
Apgar Less Than 7 Will be Sent To Examine The Umbilical Cord Blood Sample For Examination Of The Umbilical Cord PH.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: vaginal misoprostol
Category
Treatment - Drugs

2

Description
Intervention group: sub lingual misoprostol
Category
Treatment - Drugs

3

Description
Intervention group: cervical misoprostol
Category
Treatment - Drugs

4

Description
Control group: cervical placebo
Category
Placebo

5

Description
Control group: vaginal placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Somayeh Fallah
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Valiasr Street
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2

Recruitment center
Name of recruitment center
Mehregan hospital

Full name of responsible person
Somayeh Fallah
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Boali Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peimani
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Web page address
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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
Mahtab Dadashaliha
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person
Mahtab Dadashaliha

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Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
A Portion Of The Information, Such As Information On The Main Outcome Or The Like,Can be Shared.

When the data will become available and for how long
Start The Access Period 6 Months After Printing Results. "

To whom data/document is available
Only Available To Scholars Working In Academic And Academic Institutions

Under which criteria data/document could be used
If Another Clinical Trial Is Performed,The Same Is Done

From where data/document is obtainable
Email

What processes are involved for a request to access data/document
After Receiving E-mail And Proproozal And Ensuring That Information Is Not Misused

Comments
Without Elaborate