

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)

Phone

+98 28 3322 9304

Email address

m.dadashaliha@qums.ac.ir

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 \geq 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 Disease, 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 Initiationl 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

Admission 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

Admission 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

Admission 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

Admission 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

Admission 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

Admission 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

Street address

Valiasr Street

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Postal code

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Phone

+98 28 3323 6381

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Email

shimafalah@gmail.com

Web page address

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2

Recruitment center

Name of recruitment center

Mehregan hospital

Full name of responsible person

Somayeh Fallah

Street address

Boali Street

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Province

Qazvin

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Web page address<http://www.qums.ac.ir/Portal/Home/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peimani

Street address

Qazvin University Of meical Science

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Email

shimafalah@gmail.com

Web page address<http://www.qums.ac.ir/Portal/Home/>**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 scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

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Position

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Qazvin University of Medical Sciences

Full name of responsible person

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Position

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Web page address

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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