Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

the effect of misoprostol with and without letrozole in successful Induction of medical abortion and its relation with BHCG titrage and cervical length

Protocol summary

Study aim

• Determining the effect of misoprostol alone in inducing successful medical abortion • Determining the effect of misoprostol with letrozole in inducing successful medical abortion • Determining the effect of misoprostol alone in inducing successful medical abortion and its relationship with BHCG titration levels • Determining the effect of misoprostol with letrozole in inducing successful medical abortion and its relationship with BHCG titration levels • Determining the effect of misoprostol alone in inducing successful medical abortion and its relationship with cervical length • Determining the effect of misoprostol with letrozole in inducing successful medical abortion and its relationship with cervical length • Comparison of the effect of misoprostol with and without letrozole in inducing successful medical abortion and its relationship with cervical length • Comparison of the effect of misoprostol with and without letrozole in inducing successful medical abortion and its relationship with BHCG titration levels

Design

The study will be performed by randomization with block and rand function of Excel software with parallel, two-way blind groups, phase 2-3 on 120 patients.

Settings and conduct

comparative effect of misoprostol with and without letrozole in pregnant mothers> 18 weeks and abortion candidate in Sayad Shirazi Hospital in Gorgan by double-blind randomization and clinical trial with blinding the researcher and patient from the drug.

Participants/Inclusion and exclusion criteria

• Pregnant women candidates for termination of pregnancy under 18 weeks of gestation • Missed abortions • Legal and medical abortions • Single pregnancy • Hemoglobin level> 10 g/ l

Intervention groups

group A (recipients of misoprostol with letrozole) and group B (recipients of misoprostol with placebo)

Main outcome variables

Successful abortion of the fetus;Cervical length ;BHCG titration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200702047985N1**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date

2020-07-16, 1399/04/26

Registrant information

Name

Samaneh Mohammadreza khani

Name of organization / entity

Country

Iran (Islamic Republic of)

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mrkhn1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-09, 1399/04/19

Expected recruitment end date

2021-03-09, 1399/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of misoprostol with and without letrozole in successful Induction of medical abortion and its relation with BHCG titrage and cervical length

Public title

the effect of misoprostol in successful Induction of medical abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women candidates for termination of pregnancy under 18 weeks of gestation Missed abortions Legal and medical abortions Single pregnancy Hemoglobin level> 10 g/ l There should be no history or evidence of adrenal pathology, malignancies, porphyria, thromboembolism, severe or recurrent liver disease, or gestational pruritus Being consent to participate in the study

Exclusion criteria:

Any sensitivity to misoprostol and letrozole Having an intrauterine device Having a history of more than 2 cesarean sections Any abnormalities in pre-treatment blood tests, including CBC, liver and abnormalities in kidney function tests, including blood urea, creatinine, albumin, globulin, liver enzymes, and electrolytes Specific medical conditions such as severe anemia, coagulation disorders, active liver disease, cardiovascular disease, glaucoma, and uncontrolled seizure disorders Having a history of thromboembolism, adrenal diseases, steroid-dependent cancer, porphyria, and disorders that require treatment with glucocorticoids, such as bronchial asthma

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after obtaining informed consent from patients, participants will be randomized using Block Randomization method into two groups, including group A (recipients of misoprostol with letrozole) and group B (recipients of misoprostol with placebo). In this way, all possible quadruple blocks (120 blocks) that include two groups are written, and each number is assigned to one of the blocks of the table and thus represents its particular state. Randomly, based on the table of random numbers obtained by the computer program, a block will be selected, then based on that, the samples will enter into the different groups of the study. This work will be continued until we reach a sufficient number of samples in each group (4 blocks will be selected by 42 times applying the permutation method.) For example, if block 1 will be selected in the first selection, this means that the first two samples should enter group A, and the third and fourth samples should enter group B. Likewise, the block will be selected again for the next 4 samples. Also during the randomization, matching between the two groups should be applied in terms of age, maternal parity, type of delivery, history of previous miscarriage, fetal anomaly and fetal death (Fetal Death) and the above cases should be included in both groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications will be given to patients in a similar form and package by a clinical caregiver, and the researcher will only evaluate patients and evaluate the consequences.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Science

Street address

Ethics Committee of the Vice Chancellor for Research and Technology, 3rd Floor, School of Dentistry, Golestan University of Medical Sciences, Shast Kola Road, Gorgan, Iran

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Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.Goums.Rec.1399.076

Health conditions studied

1

Description of health condition studied
medical Abortion
ICD-10 code
O02.1
ICD-10 code description
Missed abortion

Primary outcomes

1

Description
Percentage of induction of successful fetal abortion with transvaginal ultrasound
Timepoint
group A members will receive up to 10 mg letrozole (2.5 mg letrax tablets, made by Abu Reihan Pharmaceuticals [Iran]) on days 1 to 3. Group B members will also receive placebo tablets, similar in appearance and taste to letrozole tablets , on days 1 to 3 .finally all patients will undergo transvaginal ultrasound on the fifth day after medical therapy
Method of measurement
Transvaginal ultrasound for successful abortion and BHCG check

Secondary outcomes

1

Description
Side Effects of Misoprostol
Timepoint
During the study, blood pressure, heart rate and patient temperature will be checked every four hours by the ward nurse and side effects including fever (body temperature more than 38 degrees of Celsius), sweating, hot flashes, arthralgia and fatigue, nausea, vomiting, bone pain, dizziness, muscle aches, diarrhea, abdominal pain, stomach pain, vaginal bleeding, sore throat, pain when urinating, difficulty in urinating, cough, rash, flu-like symptoms, difficulty in sleeping or in staying asleep, amount of bleeding, and the time of discarding of the residual tissue will be recorded by the resident and these data will be written in the patient's dossier.
Method of measurement
Measuring fever with a thermometer and measuring blood pressure with a cuff pressure gauge, clinical examinations and a history of the patient

Intervention groups

1

Description
Intervention group: Receptors of misoprostol and letrozole/). group A members will receive up to 10 mg letrozole (2.5 mg letrax tablets, made by Abu Reihan Pharmaceuticals [Iran]) on days 1 to 3. then on the morning of the third day of the study and will receive 800 micrograms of misoprostol (200 microgram misoglandin tablets, made by Samisaz Pharmaceuticals of Iran), including four 200 microgram tablets, vaginally
Category
Treatment - Drugs

2

Description
Control group: recipients of misoprostol and placebo/Group B members will also receive placebo tablets, similar in appearance and taste to letrozole tablets produced by the Isfahan School of Pharmacy, on days 1 to 3 .then on the morning of the third day of the study and will receive 800 micrograms of misoprostol (200 microgram misoglandin tablets, made by Samisaz Pharmaceuticals of Iran), including four 200 microgram tablets, vaginally
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sayad Shirazi Hospital in Gorgan
Full name of responsible person
Dr. Moghadase Jahanshahi
Street address
Women's Clinic and Obstetrics and Gynecology Department, 2nd floor, Shahid Sayad Shirazi Hospital, Sayad Shirazi Blvd., Bahonar Square, Gorgan, Iran
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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
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Dr Moghadase Jahanshahi

Position
Assistant Professor

Latest degree
Specialist

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
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Latest degree
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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
No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

• Information obtained from patients will be confidential and only accessible by the investigators and after the study is completed, only part of it will cover the main implications.

When the data will become available and for how long

Data access period begins 3 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Any statistical analysis on the data is possible.

From where data/document is obtainable

Dr. Samaneh Mohammad Reza Khani, Email Address: mrkhn13662gmail.com phone number: 09129487710

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

If the applicant states the purpose of receiving the data and submits a proposal file related to the subject of his / her present study in a copy to the project executor, the file will be received after two weeks.

Comments