Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effect of misoprostol with and without letrozole as premedication on induction of abortion in pregnant women with missed abortion at their first trimester of pregnancy

Protocol summary

Study aim
The Impact Of Letrozole With &Without Misoprostol As a Premedication In Induction Of Abortion In MISSED ABORTION before 12 weeks

Design
Two arm parallel group (63 patients in each group)randomised clinical trial with blinded outcome assessment.double blinded

Settings and conduct
The trial was done on the missed-aborted patient with gestational age less than 12 week, who came to the ALZAHRA AND SHAHID SADOUGHI HOSPITAL ,ISFAHAN,IRAN

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age less than 12 weeks Patients with missed aborted Acceptance of patients Age above 18 years Hemoglobin above 12 No evidence of renal or hepatic impairment Exclusion criteria: RENAL OR hepatic or adrenal impairment Coagulation abnprmality Peresent of IUD Cardiovascular disease Classic scar (t shape) on the uterus

Intervention groups
Missed aborted ,Pregnant women before 12 weeks devided in two groups intervention group received misoprostol+letrozol control group received misoprostol+placebo

Main outcome variables
Time interval of induction to abortion Incidence of abortion Misoprostol_+ letrozol

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190730044380N1**
Registration date: **2019-11-11, 1398/08/20**
Registration timing: **retrospective**

Last update: **2019-11-11, 1398/08/20**
Update count: **0**

Registration date
2019-11-11, 1398/08/20

Registrant information

Name
Maryam Goharian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3266 9201

Email address
mrym.gn72@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-08-22, 1395/06/01

Expected recruitment end date
2018-10-25, 1397/08/03

Actual recruitment start date
2016-10-22, 1395/08/01

Actual recruitment end date
2019-05-23, 1398/03/02

Trial completion date
2019-06-23, 1398/04/02

Scientific title
Evaluation of the effect of misoprostol with and without letrozole as premedication on induction of abortion in pregnant women with missed abortion at their first trimester of pregnancy

Public title

Evaluation of the effect of misoprostol with and without letrozol in missed aborted

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1:Gestational age less than 12 week(confirmed with ultrasonogarphy) patient with missed abortion (confirmed with ultrasonography) acceptance of participant patient age above 18 years old hemoglobin above 12

Exclusion criteria:

Clinical manifestation or history of adrenal gland impairment History of any malignancy History or clinical evidence of any thromboembolic impairment History of hepatic or renal diseases Have IUD History of cardiovascular disease that prescription of misoprostol or letrozol forbidden based on cardiologist opinion. History of use corticosteroid Present of classic scar or t shape scar on the uterus Impairment of coagulation test

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **126**

Actual sample size reached: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Random sequence generation Used random allocation software Allocation concealment ;Sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Double -blinded Participants and researcher and outcome assessor who was same as the researcher were blinded. Participants were divided into two random groups after informed consent, and then the drug was administered without knowing the nature of the drug being prescribed. To blind the researcher, the researcher was not present at the beginning and at the time of administration of the drug and was prescribed by a clinical caregiver and a clinical caregiver was present

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfahan University of Medical Sciences

Street address

SOFFEH blvd,alzahra hospital

City

ISFAHAN

Province

Isfehan

Postal code

8174675731

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.MUI.REC.1396.3.243

Health conditions studied

1

Description of health condition studied

Missed abortion

ICD-10 code

O02.1

ICD-10 code description

Missed abortion

Primary outcomes

1

Description

PRESENT OF ABORTION:COMPLETE,in complete

Timepoint

every 12 hours

Method of measurement

ultrasonography

Secondary outcomes

1

Description

time interval from induction to abortion

Timepoint

hours

Method of measurement

questionaire

Intervention groups

1

Description

Intervention group: missed aborted women with geatational age less than 12 weeks- The case group

received 10 mg of letrozole daily for three days, then received 800 µg of vaginal misoprostol, and finally received the same dose of misoprostol after four hours

Category

Treatment - Drugs

2

Description

Control group: missed aborted women with geatational age less than 12 weeks-The CONTROL group calcium carbonate tablet daily for three days, then received 800 µg of vaginal misoprostol, and finally received the same dose of misoprostol after four hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
DR.Maryam Goharian

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Soffeh blvd

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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
DR.Haghjou

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Maryam Goharian

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

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Person responsible for updating data

Contact

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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
information of main consequence can be shared

When the data will become available and for how long
1 YEAR after publish of the result

To whom data/document is available
academic researcher

Under which criteria data/document could be used
in clinical research

From where data/document is obtainable
mrym.gn72@gmail.com

What processes are involved for a request to access data/document
about 1 mounth

Comments