Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of intrauterine misoprostol administration with sublingual in second trimester abortions induction

Protocol summary

Study aim

Comparison of the effect of intrauterine misoprostol administration with sublingual in second trimester abortions induction

Design

This is a clinical trial study on 86 patients. Patients will be randomly divided into two groups 1 and 2 in parallel based on the random score assigned by rendomizer software. The researcher and analyst will be blinded in this study.

Settings and conduct

This study is performed in Tabriz University of Medical Sciences. In this study, all pregnant women with a gestational age of 12 to 22 weeks who are candidates for legal abortion included in the study. This study is performed as a randomized Double-blind clinical trial .Data collection is completed by the questioner which is done through a checklist.The sample size was 86 people. are randomly divided in two equal groups 1 and 2.

Participants/Inclusion and exclusion criteria

Women with the indication of termination of pregnancy will be included in the study in the second trimester and will be excluded from the study if they have coagulation problems and a history of cesarean section.

Intervention groups

The first group includes intrauterine administration of misoprostol. A catheter under direct vision and by using the vaginal speculum will be entered the uterine space through the endocervix and 500 micrograms of misoprostol, 2 tablets of 200 micrograms, a tablet of 100 micrograms will be Dissolved in saline under sterile conditions at a rate of 20 drops per minute equivalent to 1 micrograms will be constantly infused and this infusion will be continued until the fetus is expelled or the catheter is expelled. In the second group, misoprostol pills will be prescribed sublingually based on gestational age according to the FIGO protocol

Main outcome variables

The interval between the onset of abortion induction and the expulsion of pregnancy products is considered to be the main consequence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013777N3**
Registration date: **2022-07-08, 1401/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-08, 1401/04/17**
Update count: **0**

Registration date

2022-07-08, 1401/04/17

Registrant information

Name

Shamsi Abbasalizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

abbasalizadehs@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-01, 1401/04/10

Expected recruitment end date

2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intrauterine misoprostol administration with sublingual in second trimester abortions induction

Public title

Comparison of the effect of intrauterine misoprostol administration with sublingual in second trimester abortions induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 16 years Gestational age 14 to 22 weeks based on first trimester ultrasound Consent to participate in the study Having an indication for termination of pregnancy

Exclusion criteria:

Coagulation disorders or taking anticoagulant Possibility of ectopic pregnancy Probability of molar pregnancy Women with an IUD Women with a history of one or more cesarean sections or a history of uterine incision or myoctomy Pregnancy of placenta peria Parity 5 times or more

Age

From **16 years** old

Gender

Female

Phase

2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are divided into two intervention groups using simple randomization method.The randomization method used in this study is the use of a table of random numbers.Random number table is a set of numbers that is generated without a specific pattern or order and they generated randomly and they are formed in a table.In first the direction of reading the numbers was specified.To read the numbers, random numbers are read from the left side of the table, then even numbers extracted from the table are allocated to intervention group 1 and odd numbers extracted from the table are allocated to intervention group 2.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patient numbers will be randomly distributed in two groups, in a ratio of 1: 1 and will be kept inside a sealed envelope.The assistant of the researcher who is not in contact with the patients and will only be responsible for keeping the envelopes will announce how to induce the abortion after the call of the researcher based on the number assigned to the patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

تبریز

Province

East Azarbaijan

Postal code

5166616471

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.160

Health conditions studied

1

Description of health condition studied

Therapeutic Abortion

ICD-10 code

O04

ICD-10 code description

Therapeutic/Medical Abortion (termination of pregnancy)

Primary outcomes

1

Description

The time interval between induction of abortion and excretion of pregnancy products

Timepoint

From the beginning of the intervention until the complete rejection of the fetus

Method of measurement

Clinical examination and ultrasound

Secondary outcomes

1

Description
Fever
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Thermometer

2

Description
Nausea
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

3

Description
Vomiting
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

4

Description
Chills
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

5

Description
chills
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

6

Description
Headache
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

7

Description
Skin rash
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

8

Description
Dizziness
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

9

Description
Dfficulty breathing
Timepoint
Every 4 hours from the beginning of the intervention until the complete abortion of the fetus
Method of measurement
Clinical examination

Intervention groups

1

Description
The first group includes intrauterine administration of misoprostol. A catheter under direct vision and under sterile conditions using chlorhexidine or betadine by using the vaginal speculum will be entered the uterine space through the endocervix and its balloon will be dilated with 30 cc of sterile saline or sterile distilled water. The infusion set will be connected to a Foley catheter and a 50 cc solution containing 500 micrograms of misoprostol (manufactured by Abu Reihan-Iran Pharmaceutical Company), 2 tablets of 200 micrograms, a tablet of 100 micrograms will be Dissolved in saline under sterile conditions at a rate of 20 drops per minute equivalent to 1 micrograms will be constantly infused and this infusion will be continued until the fetus is expelled or the catheter is expelled.
Category
Treatment - Drugs

2

Description
Intervention group 2: In the second group, misoprostol 400 microgram tablets (manufactured by Abu Reihan-Iran Pharmaceutical Company) are administered sublingually every 4 hours with control of vital signs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Shamsi Abbasalizadeh

Street address
Alzahra Hospital, South Artesh St.,Tabriz, iran

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East Azarbaijan

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5138665793

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alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person
Dr Parviz Shahabi

Street address
Vice chancellor for Research,Tabriz University Of Medical Sciences

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research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Shamsi Abbasalizadeh

Position
Professor Of Obstetricians and Gynecologists

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Professor Of Obstetricians and Gynecologists
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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