

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Combined effect of dexamethasone, hyoscine and misoprostol drugs during therapeutic or legal abortion in patients visiting Imam Khomeini Hospital in Tehran

Protocol summary

Study aim

Effect of the combined effect of dexamethasone and hyoscine with misoprostol during therapeutic or legal abortion in patients visiting Imam Khomeini Hospital in Tehran.

Design

The study is conducted at Imam Khomeini Hospital in Tehran. In this study, 75 women diagnosed with medical or legal abortion from the time of approval of the plan until reaching the desired sample size are included in the study.

Settings and conduct

Individuals are assigned to three study groups (A: misoprostol, B: misoprostol + dexamethasone, and C: misoprostol + hyoscine) using a random allocation table and block classification. Misoprostol is according to Figo protocol and is used vaginally. Dexamethasone and hyoscine are administered intramuscularly, and placebo intramuscular injection is performed for the misoprostol group alone.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women aged 25-45 who have become pregnant spontaneously and the need for a therapeutic or legal abortion has been definitively diagnosed. Exclusion criteria: drug sensitivity, presence of intrauterine device (IUD), severe anemia, coagulation disorder or use of anticoagulants, active liver disease, cardiovascular disease, uncontrolled seizures, adrenal disease with high blood pressure, use Steroid drugs.

Intervention groups

The three pharmacological interventions are as follows:
1. The first group (A) receiving misoprostol
2. The second group (B) receiving misoprostol + dexamethasone
3. The third group (C) receiving misoprostol + hyoscine
The non-blinded clinical trial (only the patients are not aware of the group allocation) includes 75 people who are randomly divided into 3 equal intervention groups of 25.

Main outcome variables

Examining and comparing the amount of pain, the amount of bleeding, the success of medical abortion and the time required to perform an abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039247N9**

Registration date: **2024-01-04, 1402/10/14**

Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**

Update count: **0**

Registration date

2024-01-04, 1402/10/14

Registrant information

Name

Marjan Ghaemibidgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 4858

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Combined effect of dexamethasone, hyoscine and misoprostol drugs during therapeutic or legal abortion in patients visiting Imam Khomeini Hospital in Tehran

Public title
Combined effect of dexamethasone, hyoscine and misoprostol drugs during therapeutic or legal abortion in patients visiting Imam Khomeini Hospital in Tehran

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
pregnant woman aged 25-45 who has become pregnant spontaneously and the necessity of performing a therapeutic or legal abortion has been definitively diagnosed. Patient's awareness and acceptance of two medical and surgical methods and complications resulting from each of them Intrauterine pregnancy with a gestational age of 14 weeks or less based on ultrasound or the date of the last menstrual period a reason to terminate the pregnancy (missed abortion, blighted ovum, therapeutic abortion)
Exclusion criteria:
Allergy to Drug IUD (intrauterine device) severe anemia coagulation disorder or use of anticoagulants uncontrolled seizures adrenal disease with high blood pressure cardiovascular disease active liver disease use Steroid drugs

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are assigned to three study groups (A: misoprostol, B: misoprostol + dexamethasone, and C: misoprostol + hyoscine) using a random allocation table and block classification. The randomization list will be administered using identical, sequentially numbered study drug containers, and these containers will be identically labeled by two investigators who will not be involved in the recruitment of study subjects. The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The blocks will be 3 alleles of size 6

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

East Bagherkhan Street

City

Tehran

Province

Tehran

Postal code

14146

Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.289

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

O02.1

ICD-10 code description

Missed abortion

Primary outcomes

1

Description

Comparison of intervention in the amount of patient pain during abortion, comparison of intervention in the amount of patient bleeding during abortion, comparison of intervention in the time required for abortion

Timepoint

The amount of bleeding and the time required are measured at the end of the process.

Method of measurement

The amount of bleeding is measured based on the patient's pads and the time is measured based on hours and minutes.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vaginal misoprostol 400 micro every 4 hours until abortion

Category

Treatment - Drugs

2

Description

Intervention group: Vaginal misoprostol 400 micrograms every 4 hours + dexamethasone 8 mg intravenous injection (with the first dose of misoprostol)

Category

Treatment - Drugs

3

Description

Intervention group: Vaginal misoprostol 400 micrograms every 4 hours + one dose of hyosin 20 mg intravenous injection (with the first dose of misoprostol)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Marjan Ghaemi

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East Bagherkhan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Marjan Ghaemibidgoli

Position

Assisted professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marjan Ghaemibidgoli

Position

Assisted professor

Latest degree