

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The efficacy of medical versus surgical abortion for first trimester therapeutic in Iran; A quasi experimental analysis

#### Protocol summary

##### Study aim

Comparison of the effectiveness of medical versus surgical strategy for first trimester therapeutic abortion

##### Design

Non-randomized controlled trial (quasi experimental analysis), with control group, parallel group, without blinding, on 140 women (70 for each group)

##### Settings and conduct

This study are performing with the participation and supervision of a gynecologist on patients referred to Akbarabadi Mothers Support Center, Hazrat Rasoul Akram Hospital and Firoozgar Hospital in Tehran during early six months of persian new year.

##### Participants/Inclusion and exclusion criteria

Women seeking first trimester therapeutic abortion at the age 18 to 45 without underlying diseases particularly the cancers

##### Intervention groups

The intervention group includes women who use the drug method (misoprostol) to perform the treatment process of abortion, The control group includes women who use surgery (curettage) to perform abortion treatment.

##### Main outcome variables

Success rate of abortion treatment in the first trimester of pregnancy, possible complications of each intervention including severe bleeding, infection, uterine injury

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210916052504N1**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **prospective**

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

##### Registration date

2021-11-20, 1400/08/29

##### Registrant information

###### Name

Saeed Husseini Barghazan

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8867 1615

###### Email address

hoseyni.sa@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of medical versus surgical abortion for first trimester therapeutic in Iran; A quasi experimental analysis

##### Public title

The efficacy of medical versus surgical abortion for first trimester therapeutic in Iran; A quasi experimental analysis

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women seeking first trimester therapeutic abortion

### Exclusion criteria:

Illegal abortions Underlying disease (including neoplasms)

## Age

From **18 years** old to **45 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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 Iran University of Medical Sciences

##### Street address

School of Health Management and Information Sciences, No. 6, Rashid Yasemi St. Vali -e Asr Ave, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1996713883

#### Approval date

2020-04-06, 1399/01/18

#### Ethics committee reference number

IR.IUMS.REC.1399.068

## Health conditions studied

### 1

#### Description of health condition studied

Missed abortion

## ICD-10 code

O02.1

## ICD-10 code description

Missed abortion

### 2

#### Description of health condition studied

Complications following (induced) termination of pregnancy

## ICD-10 code

O04

## ICD-10 code description

Complications following (induced) termination of pregnancy

### 3

#### Description of health condition studied

(Induced) termination of pregnancy with other and unspecified complications

## ICD-10 code

O04.8

## ICD-10 code description

(Induced) termination of pregnancy with other and unspecified complications

## Primary outcomes

### 1

#### Description

Success rate of abortion treatment in the first trimester of pregnancy termination

#### Timepoint

The patient's clinical condition based on the physician's opinion 14 days after receiving the first medication or surgery

#### Method of measurement

Questionnaire, test, imaging and doctor's opinion

## Secondary outcomes

### 1

#### Description

Possible side effects of treatment include severe bleeding, need to repeat the abortion process, infection or damage to the uterus

#### Timepoint

Clinical status of the patient 14 days after receiving the first treatment intervention

#### Method of measurement

Questionnaire, test, imaging and doctor's opinion

## Intervention groups

### 1

#### Description

Medical intervention with three doses of misoprostol 400 mg (with trade name Cytotec) sublingual and vaginal 6

hours apart

**Category**

Treatment - Drugs

**2**

**Description**

Dilation and curettage (D & C), the dilation of the cervix and surgical removal of part of the lining of the uterus and/or contents of the uterus by scraping and scooping along with 200 mg of misoprostol at the time of surgery and 6 hours after that

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hazrate Rasool Akram Hospital

**Full name of responsible person**

Mohamad Hadian

**Street address**

Hazrate Rasool Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN

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**2**

**Recruitment center**

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Mohamad Hadian

**Street address**

Firoozgar Hospital, Beh afarin St, Karimkhan St, Valiasr aquare, Tehran, IRAN

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**3**

**Recruitment center**

**Name of recruitment center**

Akbarabadi Hospital

**Full name of responsible person**

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**Street address**

Akbarabadi Hospital, Bagferdos Bus Station, Molavi St, Tehran, IRAN

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mohamad Hadian

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Saeed Husseini Barghazan

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Health Economy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Setare Nassiri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

This research is part of the dissertation of the PhD course in Health Economics, which is conducted at Iran University of Medical Sciences. Any sharing is done by this university.

**When the data will become available and for how long**

Second six month of 1401, central library of iran university of medical sciences

**To whom data/document is available**

In order to facilitate decisions at the level of the health system and policy makers, by physicians or patient preferences, as well as the researchers

**Under which criteria data/document could be used**

In order to facilitate decisions at the level of the health system and policy makers, by physicians or patient preferences

**From where data/document is obtainable**

Website or Central Library of Iran University of Medical Sciences

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

Website or Central Library of Iran University of Medical Sciences

## Comments