

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### The comparative evaluation of the effect of sublingual misoprostol versus wet cervical misoprostol on duration of abortion in patients candidates for abortion in early second Trimester

#### Protocol summary

##### Study aim

The Determination of the effect of wet cervical and sublingual Misoprostol on duration of abortion in patients candidates for early second Trimester Abortion

##### Design

Clinical trial , with parallel groups, randomized

##### Settings and conduct

This study is performed in Qazvin University of Medical Sciences. In this study, all pregnant women with a gestational age of 12 to 20 weeks who are candidates for legal abortion and referred to Kowsar and Mehregan hospitals in Qazvin are examined and included in the study. This study is performed as a randomized single-blind clinical trial (participant in the project). Data collection is completed by the questioner which is done through a checklist. The sample size was 200 people. If they meet the inclusion criteria, enter the study and are randomly divided into two equal groups a and b.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria : Unifetal pregnancy , Missed abortion , Fetal malformations , Blighted ovum, Trisomies , Gestational age ( 12 weeks and less than 12 weeks ) ; Exclusion Criteria : Rupture of membrane , History of cesarean section more than once, History of allergy to misoprostol and prostaglandins , Contraindications of prostaglandin use ( like heart disease, kidney disease, history of seizures and hypotension )

##### Intervention groups

Intervention group a: This group will receive 200 micrograms of sublingual Misoprostol brand (Cytotec, Searle, England) with cervical placebo (alborz daroo) . intervention group b: will receive 200 micrograms of cervical Misoprostol (Cytotec, Searle, England) Moisturized with water, with sublingual placebo (alborz daroo). then in both groups, the mentioned dose will be repeated every 4 hours until the abortion and the maximum duration of administration of drug will be up to

48 hours.

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046280N2**

Registration date: **2020-10-17, 1399/07/26**

Registration timing: **prospective**

Last update: **2020-10-17, 1399/07/26**

Update count: **0**

##### Registration date

2020-10-17, 1399/07/26

##### Registrant information

##### Name

Amirhossein Gholamlou

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6655 6253

##### Email address

a.gholamlou@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The comparative evaluation of the effect of sublingual misoprostol versus wet cervical misoprostol on duration of abortion in patients candidates for abortion in early second Trimester

**Public title**  
The Comparative evaluation of effect of Sublingual Misoprostol versus cervical misoprostol on second Trimester abortions

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Unifetal pregnancy Missed abortion Fetal malformations Blighted ovum Trisomies Gestational age ( 12 weeks and less than 12 weeks )  
**Exclusion criteria:**  
Rupture of membrane History of cesarean section more than once History of allergy to misoprostol and prostaglandins Contraindications of prostaglandin use ( like heart disease, kidney disease, history of seizures and hypotension )

**Age**  
From **16 years** old to **45 years** old

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **200**

**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 a and odd numbers extracted from the table are allocated to intervention group b.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants are unaware of treatment allocation and are divided into groups a and b. Group a receives sublingual misoprostol with cervical placebo and group b receives

cervical misoprostol with sublingual placebo. Finally, the results of the work are filled by the midwife of the ward, using the questionnaire form and provided to the researcher.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qazvin University Of Medical Science

##### Street address

No 4, mavedat ave, shahid beheshti blvd

##### City

Qazvin

##### Province

Qazvin

##### Postal code

1391134156

#### Approval date

2020-01-25, 1398/11/05

#### Ethics committee reference number

IR.QUMS.REC.1398.279

## 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

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

#### Timepoint

After intervention and then every one hour

#### Method of measurement

clock

### 2

#### Description

Nausea (drug side effects)

### **Timepoint**

After intervention and then every one hour

### **Method of measurement**

Clinical examination and questioning of the patient

### **3**

#### **Description**

Vomiting (drug side effects)

#### **Timepoint**

After intervention and then every one hour

#### **Method of measurement**

Clinical examination and questioning of the patient

### **4**

#### **Description**

Fever (drug side effects)

#### **Timepoint**

After intervention and then every one hour

#### **Method of measurement**

Thermometer

### **5**

#### **Description**

Diarrhea (drug side effects)

#### **Timepoint**

After intervention and then every one hour

#### **Method of measurement**

Clinical examination and questioning of the patient

### **6**

#### **Description**

Headache (drug side effects)

#### **Timepoint**

After intervention and then every one hour

#### **Method of measurement**

Clinical examination and questioning of the patient

### **7**

#### **Description**

abortion type (Complete or incomplete)

#### **Timepoint**

After intervention and then every one hour

#### **Method of measurement**

Clinical examination with speculum and doing ultrasonography

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

First intervention group (group a): This group will receive 200 mcg of sublingual misoprostol from the brand (Cytotec, Searle, England) along with cervical

placebo(alborz daroo company) and then the mentioned dose will be repeated every 4 hours until the abortion.The maximum duration of drug administration will be up to 48 hours.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2 (group b): This group will receive 200 mcg of cervical misoprostol from brand (Cytotec, Searle, England) moistened with a few drops of distilled water along with sublingual placebo(alborz daroo company) and then the mentioned dose is repeated every 4 hours until abortion. The maximum duration of drug administration will be up to 48 hours.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Kowsar hospital

##### **Full name of responsible person**

Masoumeh Dadashaliha

##### **Street address**

Kowsar Hospital, Kowsar Alley, next to the electricity office, Taleghani St

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3415613176

##### **Phone**

+98 28 3323 6376

##### **Fax**

+98 28 3323 6376

##### **Email**

dadashaliham@yahoo.com

##### **Web page address**

<http://www.qums.ac.ir/Portal/Home/>

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Mehregan hospital

##### **Full name of responsible person**

Masoumeh Dadashaliha

##### **Street address**

Mehregan Hospital, next to Dialysis Center, Ferdowsi St.

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3413786573

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mahdi Emamjomeh

**Street address**

Qazvin University Of medical Science ,Shahid Bahonar Blvd.

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Qazvin

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Qazvin

**Postal code**

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**Phone**

+98 28 3333 6001

**Fax**

+98 28 3333 6001

**Email**

medicine@qums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Masoumeh Dadashaliha

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No. 2, Bahar Doctors Building ,East Bouali St.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3491658875

**Phone**

+98 28 3322 9304

**Email**

dadashaliham@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Masoumeh Dadashaliha

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Masoumeh dadashaliha

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Province**

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**Postal code**

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**Phone**

+98 28 3322 9304

**Email**

dadashaliham@yahoo.com

## Sharing plan

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

Yes - There is 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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

A part of the data, such as information about the main outcome, can be shared.

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

Access period starts 6 months after publishing the results.

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions

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

If another similar clinical trial is performed

**From where data/document is obtainable**

Email

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

After receiving the email and the proposal and ensuring that the information is not misused

**Comments**