Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

The comparative evaluation of the effect of sublingual and cervical misoprostol on the duration of abortion in patients candidate for abortion in the first trimester of pregnancy

Protocol summary

Study aim
The Determination of the effect of sublingual and cervical misoprostol on the the abortion rate and duration of abortion in the first trimester of pregnancy in patients candidate for abortion

Design
Clinical trials , 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 1 to 12 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, Multifetal pregnancy, History of allergy to misoprostol and prostaglandins , Contraindications of prostaglandin use (like heart disease, kidney disease, history of seizures and hypotension)

Intervention groups
At the beginning , patients of group A will receive 400 micrograms of sublingual misoprostol along with cervical placebo and , patients of group b will receive 400 micrograms of wet ted cervical misoprostol along with sublingual placebo, and then the dose is repeated every 4 hours until the abortion, and the maximum duration of administration of the 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: **IRCT20200127046280N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **prospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date
2020-10-16, 1399/07/25

Registrant information

Name
Amirhossein Gholamlou

Name of organization / entity

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Iran (Islamic Republic of)

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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 and cervical misoprostol on the duration of abortion in patients candidate for abortion in the first trimester of pregnancy

Public title
The comparative evaluation of the effect of sublingual and cervical misoprostol on first trimester abortion
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 Multifetal pregnancy 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.1398.280

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 and questioning of the patient

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group (group a): This group will receive 400 mcg of sublingual misoprostol from the brand (Cytotec, Searle, England) along with cervical placebo 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 400 mcg of cervical misoprostol from brand (Cytotec, Searle, England) moistened with a few drops of distilled water along with sublingual placebo 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
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2

Recruitment center
Name of recruitment center
Mehregan hospital
Full name of responsible person
Masoumeh Dadashaliha
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Mehregan Hospital, next to Dialysis Center, Ferdowsi St.
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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

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Qazvin University Of medical Science ,Shahid Bahonar Blvd.

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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
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

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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

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 E-mail And Proposal And Ensuring That Information Is Not Misused

Comments