Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Aug 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
Phone
+98 28 3336 5160
Fax
+98 28 3336 5160
Email
dadashaliham@yahoo.com
Web page address
http://www.qums.ac.ir/Portal/Home/

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.
City
Qazvin
Province
Qazvin
Postal code
5981134197
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
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 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
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

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