

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of misoprostol compared with Stachys lavandulifolia with misoprostol on the rate of abortion in the first trimester

Protocol summary

Study aim

Evaluation of the effect of misoprostol compared with Stachys lavandulifolia with misoprostol on the rate of abortion in the first trimester

Design

clinical trial with control group; With Parallel groups; Double blinded; randomized; design of 40 patients

Settings and conduct

Eligible patients entering the study referred to Imam Sajjad Hospital of Yasuj University of Medical Sciences will be divided into two groups of 20 people and the consequences of abortion will be measured.

Participants/Inclusion and exclusion criteria

Uterine size in proportion to gestational age on clinical examination Candidates for termination of pregnancy for reasons such as missed abortion, blighted ovum, or fetal death can be confirmed by two ultrasounds. Age between 18 to 45 years Gestational age less than 12 weeks gestation No contraindication to use of misoprostol No history of uterine pathology ultrasound findings No mole pregnancy

Intervention groups

Group A: Stachys lavandulifolia extract will be administered in the form of tablets (400 mg every three hours, up to three doses) along with 400 micrograms (up to three doses every three hours). If the fetus is not expelled, the above dose will be repeated on the second day. In group B: Misoprostol will be prescribed according to the latest national protocol guidelines. In this way, 800 micrograms (four 200 microgram tablets) every three hours, up to three doses) will be used orally. If the fetus is not aborted, the above dose will be repeated on the second day.

Main outcome variables

Completed abortion Incompleted abortion Hemorrhage Pain severity

General information

Reason for update

Hi Respectfully recalls the present study entitled "Comparison of the effect of misoprostol in comparison with Stachys lavandulifolia with misoprostol in the success of the first trimester of abortion in patients referred to the maternity ward of Imam Sajjad Hospital in Yasouj in 1398" in the ethics committee of Yasouj University of Medical Sciences was confirmed that the information of the groups was entered incorrectly in the two groups of misoprostol alone and Stachys lavandulifolia alone, which was corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N7**
Registration date: **2020-07-01, 1399/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-13, 1400/01/24**

Update count: **2**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

Fatemeh Bazarganipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

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

Evaluation of the effect of misoprostol compared with Stachys lavandulifolia with misoprostol on the rate of abortion in the first trimester

Public title

Misoprostol compared with Stachys lavandulifolia with misoprostol on the rate of abortion in the first trimester

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Uterine size in proportion to gestational age on clinical examination Candidates for termination of pregnancy for reasons such as missed abortion, blighted ovum, or fetal death can be confirmed by two ultrasounds. Age between 18 to 45 years Gestational age less than 12 weeks gestation No contraindication to use of misoprostol No history of uterine pathology ultrasound findings No mole pregnancy

Exclusion criteria:

Unwillingness to participate in the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized in 4 blocks; Hiding method: Use envelopes in the package

Blinding (investigator's opinion)

Single blinded

Blinding description

The blinding method is patients will not be aware of their allocation to study groups and all medications will be placed into same capsules of size, shape and color by the pharmacist.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.YUMS.REC.1398.147

Health conditions studied**1****Description of health condition studied**

Abortion

ICD-10 code

O04.8

ICD-10 code description

(Induced) termination of pregnancy with other and unspecified complications

Primary outcomes**1****Description**

Completed abortion

Timepoint

After intervention

Method of measurement

Symptom

2**Description**

Incompleted abortion

Timepoint

After intervention

Method of measurement

Symptom

3

Description

Pain severity

Timepoint

After intervention

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Group A: Stachys lavandulifolia extract will be three doses) along with 400 micrograms (up to three doses every three hours). If the fetus is not expelled, the above dose will be repeated on the second day.

Category

Treatment - Drugs

2

Description

In group B: Misoprostol will be prescribed according to the latest national protocol guidelines. In this way, 800 micrograms (four 200 microgram tablets) every three hours, up to three doses) will be used orally. If the fetus is not aborted, the above dose will be repeated on the second day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasuj University of Medical Sciences

Full name of responsible person

Samira Kalami

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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Phone

+98 74 3333 7251

Email

dr.samirakalami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari-Oriad

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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dr.samirakalami@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Samira Kalami

Position

Student

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**

Yasouj University of Medical Sciences

Full name of responsible person

Samira Kalami

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

No more 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available