

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of vaginal misoprostol alone and vaginal misoprostol simultaneously with laminaria in induction of second trimester pregnancy (14-20 weeks) in patients referred to Imam Ali Hospital's Hospital (Clinical Practice)

Protocol summary

Study aim

This study is performed to determine the effect of vaginal misoprostol with laminaria in comparison with vaginal misoprostol alone in termination of pregnancy of the second trimester of pregnancy (14 to 20 weeks).

Design

Clinical trial with parallel control groups, one blind, randomized, On 90 patients referring to the maternity of Ali ibn Abi Talib hospital, which are 14 to 20 weeks pregnant and are a candidate for termination of pregnancy.

Settings and conduct

In the intervention group, the Laminaria will be inserted into the cervix. Then, at the same time, the misoprostol suppository contains 400 micrograms in the posterior Fornix of the vagina and examines the patient every 8 hours, and if we do not pass the fetus after 8 hours, we will repeat the vaginal misoprostol. . This process continues for up to 6 doses and, if not eliminated, until then, surgery is used to terminate the pregnancy. In the control group, misoprostol suppository 400 micrograms will be prescribed, According to the intervention group.

Participants/Inclusion and exclusion criteria

Entry requirements: Pregnant women between the weeks 14-20 weeks of pregnancy admitted to Imam Ali Hospital who are candidates for termination of pregnancy due to severe anomalies or fetal death. Single-swelling conditions, parietal 1 to 3, painless and uterine infections
Non-arrival conditions: Allergy to medications, taking anticoagulants and corticosteroids, having some special diseases, history of previous anesthetic on the uterus, parity of more than three, Peruvian pairs, and more.

Intervention groups

In the first group, Laminaria is inserted into the cervix. Together with 400 micrograms of vaginal progesterone

every 8 hours to 6 times and another 400 micrograms of vaginal progesterone every 8 hours to 6 times.

Main outcome variables

The average need for curettage, Labor time, Hospital admission time after termination of pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190529043759N1**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

Registration date

2019-07-07, 1398/04/16

Registrant information

Name

Fatemeh Behnood

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5570

Email address

dr.f.behnood@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal misoprostol alone and vaginal misoprostol simultaneously with laminaria in induction of second trimester pregnancy (14-20 weeks) in patients referred to Imam Ali Hospital's Hospital (Clinical Practice)

Public title

The Effect of Laminaria with Vaginal Misoprostol on Cervical Preparation in Induction of Second Trimester Abortion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women between 14-20 weeks of pregnancy at Imam Ali Hospital who are candidates for termination of pregnancy due to severe anomalies or due to fetal death Singleton conditions, parity 1 to 3, painless and uterine infections

Exclusion criteria:

Allergy to the drug parity of more than three severe anemia active liver disease cardiovascular disease uncontrolled seizures having IUD Placenta Previa History of cesarean section previous incision on the uterus Use of corticosteroids Use of anti coagulants

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Accidental assignment to intervention and control groups. To minimize the potential confounding effects, all participants with all the conditions for entry into the study will be randomized. Randomized blocked sampling will be based on gradual referral of eligible samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the therapist is aware of the type of treatment and Laminaria and Misoprostol should be examined by the therapist for several hours, it is a blind side effect and patients are unaware of the treatment. We also use an

assessment that does not know the treatment of the groups and we ask the evaluator for the statistics to get the statistics.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Ali Ebn Abitaleb Hospital, Persian Gulf Expressway

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.ZAUMS.REC.1398.078

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

Medical abortion

ICD-10 code

O04

ICD-10 code description

Complications following (induced) termination of pregnancy

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

Termination of pregnancy

Timepoint

Every eight hours to six times

Method of measurement

dilatation of cervix and contraction

Secondary outcomes

1

Description

Need for curettage

Timepoint

From the start, every eight hours to six turns

Method of measurement

Clinical examinations

2

Description

Abortion time in labor

Timepoint

Interval between administration of drug and expulsion of fetus

Method of measurement

Record time

3

Description

Time of admission in hospital after abortion

Timepoint

From the time of the abortion to the patient's discharge

Method of measurement

Record time

Intervention groups

1

Description

Intervention group: Embedding of Laminaria In the cervix with 400 µg Misoprostol Vaginally every 8 hours, up to 48 hours

Category

Treatment - Drugs

2

Description

Control group: 400 µg Misoprostol Vaginally every 8 hours, up to 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Taleb Hospital

Full name of responsible person

Fatemeh Behnood

Street address

Persian Gulf Highway, Salamat Blvd., Ali Ibn Abi Taleb Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

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Deputy of Research and Technology, Student Scientific Research Center, University of Medical Sciences campus, Dr. Hesabi Square, Zahedan

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Msrc@zamus.ac.ir

Web page address

<http://msrc.zaums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fatemeh Behnood

Position

Assistant Professor

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**

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

Undecided - It is not yet known if there will be 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