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 are14 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)

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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 Behnoud
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
Street address
Deputy of Research and Technology, Student Scientific Research Center, University of Medical Sciences campus, Dr. Hesabi Square, Zahedan
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Web page address
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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
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 updating data

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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