Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

comparison between herbal medicine myrrh , sesamum indicum and oral contraceptive pills for treatment of incomplete abortion

Protocol summary

Study aim
comparison between herbal medicine myrrh , sesamum indicum and oral contraceptive pills for treatment of incomplete abortion

Design
This clinical trial study has a control group, including 4 groups, including group A, LD which is a type of OCP pill, group B, Myrrhs capsule, group C, dried sesame extract capsule and the control group receiving capsules with Avicel. Treatment in groups is done in parallel. 160 patients will be randomly divided into 4 groups. The study was conducted in a double-blind manner, and the patients and the examiner of the results will not be aware of the type of drug used.

Settings and conduct
In this study, 160 patients referred to teaching and therapeutic hospitals affiliated to Shiraz University of Medical Sciences were randomly divided into four groups: group A, LD which is a type of OCP pill, group B, Myrrhs capsules, group C, capsules of dried sesame extract and group Control recipients will be divided into capsules with Avicel. In each group, all medicines will be designed in the same way and the patient will take the medicine for 14 days. The doctors and the examiner of the result will not be aware of the type of drug used. After the end of the transvaginal color Doppler ultrasound treatment, the remnants of the placenta after the abortion are examined and measured by a radiologist.

Participants/Inclusion and exclusion criteria
healthy women with a normal blood count (hemoglobin > 9) , estimated gestational age less than 20 weeks, with intrauterine tissue with an anterior posterior diameter 15-50 mm less than 1month post abortion, BMI ≤ 30

Intervention groups
Group A (n=40), LD capsule combined with Avasil Group B (n=40), Myrrhs capsule 500 mg BID Group C (n=40), capsules of dried sesame extract Group D 40 (n=40) placebo capsules (containing Avacil). In all groups, medicine (capsule) is prescribed for 14 days

Main outcome variables
incomplete abortion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240109060656N1**
Registration date: **2024-02-08, 1402/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-08, 1402/11/19**
Update count: **0**

Registration date
2024-02-08, 1402/11/19

Registrant information

Name
Mojtaba Neydavoodi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between herbal medicine myrrh , sesamum indicum and oral contraceptive pills for treatment of incomplete abortion

Public title

herbal medicine myrrh , sesamum indicum and oral contraceptive pill for treatment of incomplete abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

healthy women with a normal blood count (hemoglobin > ۹) estimated gestational age less than ۲۰ weeks with intrauterine tissue with an anterior posterior diameter ۱۵-۵۰ mm less than ۱ month post abortion BMI ≤ ۳۰ no fever no pelvic tenderness no infection in vaginal exam Age between 18 and 35 years

Exclusion criteria:

Age less than 18 and more than 35 years BMI>30 Presence of infection in vaginal examination

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

This study includes 160 patients in 4 groups. 160 patients were divided into 40 blocks of 4. Each block is numbered and will be used for 4 patients, that is, if block number 2 is selected in the lottery, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment C, and the fourth patient will receive treatment D. The fifth patient will be randomly selected from one of the blocks and the type of treatment will be assigned to the fifth to eighth patients according to the block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study was conducted in a double-blind manner, and the patients and the examiner of the results (our expert radiologist) will not be aware of the type of drug used. Each drug is placed in a box in the package with a corresponding number label so that the patient does not have any information about the type of drug used. The shape and packaging of myrrh and OCP capsules and sesame and placebo are similar. In this study, our nurse colleague in the hospital affiliated to Shiraz University of Medical Sciences will deliver medicine and placebo to the study participants based on the random block table.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-12-24, 1402/10/03

Ethics committee reference number

IR.SUMS.MED.REC.1402.429

Health conditions studied

1

Description of health condition studied

incomplete abortion

ICD-10 code

O03. 4

ICD-10 code description

Spontaneous abortion Incomplete, without complication.

Primary outcomes

1

Description

Remaining remnants of the placenta after abortion

Timepoint

After the end of 14 days of treatment

Method of measurement

Using the findings observed in transvaginal color doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group A, LD, which is a type of OCP tablet that is placed inside the capsule with Avacil and is prepared as a capsule. This capsule is prescribed for 40 patients for 14 days
Category
Treatment - Drugs

2

Description
Intervention group: Group B Myrrhs capsules to 40 patients, 500 mg BID for 14 days
Category
Treatment - Drugs

3

Description
Intervention group: Group C (n=40),Contact capsules with dried sesame extract are given to 40 patients for 14 days (BID).
Category
Treatment - Drugs

4

Description
40 patients will receive a placebo capsule (containing Avacil) for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical educational hospitals affiliated to Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Rowshani
Street address
Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Rowshani
Position
Obstetrics and Gynecology assistant student
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
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Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data related to the study will not be published

When the data will become available and for how long
Data related to the study will not be published

To whom data/document is available
Data related to the study will not be published

Under which criteria data/document could be used
Data related to the study will not be published

From where data/document is obtainable
Data related to the study will not be published

What processes are involved for a request to access data/document
Data related to the study will not be published

Comments