Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Analyze the effect of the sesamum indicum on The termination of an incomplete abortion

Protocol summary

Summary

The purpose of this study is to evaluate the effectiveness of sesame as an adjunct (auxiliary) drug in disposal of pregnancy remains. It is a randomized clinical trial without placebo control. The method is that 90 pregnant women 18-50 years old with gestational age below 20 weeks, with the symptoms of incomplete abortion admitted to Women's Hospital Moheb Yas affliated to Tehran University of Medical Sciences. After definitive diagnosis of uncomplicated incomplete abortion, by obstetricians, and after providing the necessary clarifications and considering the inclusion criteria, and filling out the questionnaire consciously, we divided the participants randomly into two groups: 45 patients only received misoprostol and 45 patients received misoprostol with sesame. In addition to misoprostol we give sesame and its preparation and consumption instructions to second group of patient (according to protocol). All patients completed follow-up clinical symptoms questionnaire at home and at the end of the second week they come for sonography. The primary outcome in this study was to determine the amount of pregnancy debris at the end of the second week, and secondary outcome examined the incidence and severity of clinical symptoms related to incomplete abortion (abdominal or pelvic pain and cramp and bleeding) and should take painkillers and antibiotics and blood transfusions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122729062N1**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name
Zahra Aghababaei
Name of organization / entity
Isfahan University of Medical Science
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analyze the effect of the sesamum indicum on The termination of an incomplete abortion

Public title

Analyze the effect of the sesamum indicum on disposal of the pregnancy remains.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteri: 1 - Pregnant women 18_50 years pld admitted to Moheb Yas women hospital of Tehran, less than 20 weeks gestational age and with clinical or ultrasound evidence of incomplete abortion. 2 - Lack of infectious abortion’s signs (a) 38 degrees fever or more (b) INDEX (c) 3 degrees fever per hour or more in the first 24 hours. 3 - Lack of any signs of Induced abortion and manipulation by the patient. 4 - Lack of repeated abortion (RPL) due to anatomical disease of mother (Septate Uterus, Unicorns uterus, short Cervix) and diagnosed chromosomal disorders of parents leading to fetal death or blighted ovum and fetal abnormalities including Malformation and Dysmorphic Show, Monosomy X. 5 -The risk of any base disease (Diabetes - blood pressure - kidney failure - heart and liver illness). 6 - Lack of signs of hemorrhagic shock Grade 1(Bleeding more than 750 cc). 7 - Lack of ectopic pregnancy. 8 - Lack of open cervical in examination. Exclusion criteria: 1 - The emergence of allergies to sesame or its components. 2 - Severe abdominal pain that require emergency intervention. 3 - Fever over 38 degrees. 4 - Sepsis that require antibiotic treatment or abortion. 5 - Severe bleeding (bleeding more than 750 CC). 6 - Unwillingness to continue cooperation.

Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib
City
Isfahan
Postal code
Approval date
2016-08-07, 1395/05/17
Ethics committee reference number
IR.MUI.REC.1395.3.616

Health conditions studied

1

Description of health condition studied
The remains of a pregnancy
ICD-10 code
O03.4
ICD-10 code description
Spontaneous abortion : incomplete, without complication

Primary outcomes

1

Description
The full disposal of the products of pregnancy
Timepoint
Two weeks after intervention
Method of measurement
Sonography

Secondary outcomes

1

Description
Amount of bleeding
Timepoint
During the intervention
Method of measurement
PBAC questionnaire

2

Description
The time of bleeding stop
Timepoint
Daily medication and the end of the second week
Method of measurement
PBAC questionnaire

3

Description
Amount and intensity of pain
Timepoint
Daily medication and the end of the second week
Method of measurement
VAS questionnaire

4

Description
Amount of painkiller
Timepoint

Daily medication and the end of the second week

Method of measurement

Researcher questionnaire

5

Description

The incidence of misoprostol’s effects

Timepoint

Daily medication and the end of the second week

Method of measurement

Researcher questionnaire

Intervention groups

1

Description

We delivered 10 packs 60 grams of sesame to the intervention group and also we trained them How to prepare and use it. For 5 days, twice a day, in the same time misoprostol tablets prescribed by obstetrician.

Category

Treatment - Drugs

2

Description

They prescribed misoprostol tablets routinely to the control group by obstetricians.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Yas Women’s General Hospital

Full name of responsible person

Zahra Aghababaie

Street address

Moheb Yas Women’s General Hospital, North Nejatollahi ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chacellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Mohammad Mazaheri

Street address

Traditional Medicine Department, Isfahan University of Medical Sciencesedical Science.

City

Isfahan

Grant name

Grant code / Reference number

395616

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

Yes

Title of funding source

Vice chacellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zahra Aghababaei

Position

PhD student of Traditional Medicine

Other areas of specialty/work

Street address

Ahmadiye clinic, Tabriz alley, north Sarparast street, Taleghani street

City

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+98 21 8897 6527

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Nejat Bakhsh

Position

PhD Assistance professor of Traditional Medicine

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty