

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Nigella sativa oil on the outcome of missed abortion in women

Protocol summary

Study aim

Determination of the effect of Nigella sativa oil on the outcome of missed abortion in women

Design

In this study, 70 patients with Missed abortion with inclusion criteria are divided into two groups. control and intravention group, the control group receive only placebo , and the intervention group receive capsul containing 5 grams of nigella sativa oil three times a day for three days. after three days the therapeutic effects of the capsule will be examined.

Settings and conduct

Clinical trial; Women's Specialty Clinic; placebo-controlled

Participants/Inclusion and exclusion criteria

Inclusion criteria: Missed abortion
Exclusion criteria: Sensitivity to Nigella sativa

Intervention groups

Intervention group: receive the herbal capsule containing 5gr Nigella sativa oil three times a day for three days. control group: receive the placebo capsule three times a day for three days.

Main outcome variables

Evacuation of pregnancy products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120709010222N21**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**

Update count: **1**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nigella sativa oil on the outcome of missed abortion in women

Public title

The effect of Nigella sativa oil on the outcome of missed abortion in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with miss abortion

Exclusion criteria:

Sensitivity to Nigella sativa

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign patients to two groups of treatment and placebo by a third person and using a computer program with simple randomization method, the random sample number is generated and each patient will be assigned a number. Even numbers will be allocated to treatment with a semi-solid product, from Nigella sativa and odd numbers to placebo

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the patient will have no information about the content of the capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology,
Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Iran

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.SKUMS.REC.1397.205

Health conditions studied

1

Description of health condition studied

missed abortion

ICD-10 code

O02.1

ICD-10 code description

Early fetal death with retention of dead fetus

Primary outcomes

1

Description

Evacuation of pregnancy products

Timepoint

three days after intervention

Method of measurement

Self-discharge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive the herbal capsule containing 5gr Nigella sativa oil three times a day for three days.

Category

Treatment - Drugs

2

Description

control group: receive the placebo capsule three times a day for three days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Belgheyse Mohammadi

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran

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+98 38 3222 0016

Email

mohammadi.b@skums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy of Shahrekord University of Medical Sciences

Full name of responsible person

Dr.Kamal Solati

Street address

Vice Chancellor of Research and Technology,
Shahrekord University of Medical Sciences,Kashani
Blvd, Shahrekord,Iran

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kamal@skums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Shahrekord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Belghese Mohammadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Kashani Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data in article format

When the data will become available and for how long

1397

To whom data/document is available

researchers

Under which criteria data/document could be used

publication

From where data/document is obtainable

journals

What processes are involved for a request to access data/document

publication of article

Comments