

# 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 capsul 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

**City**

shahrekord

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**Phone**

+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

**Street address**

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

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shahrekord

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Belghese Mohammadi

**Position**

Assistant professor

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Specialist

**Other areas of specialty/work**

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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**