Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 oilthree 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 containing5gr 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
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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

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

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