

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Nigella Sativa capsules in order to prepare endometrium for frozen embryo transfer

Protocol summary

Study aim

The effect of Nigella Sativa on endometrial preparation in frozen embryo transfer cycles

Design

A randomized, single blinded clinical trial with control and parallel groups and 116 participants

Settings and conduct

This single-blind clinical trial will be performed on 116 pregnant women referring to Milad Fertility Clinic in Mashhad who have a frozen fetus and are candidates for embryo transfer. These patients are randomly divided into two groups using computer-generated table of random numbers. In this single-blind study, participants are not aware of the type of grouping and the received treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women between 20 and 42 years old with a frozen fetus who are candidate for embryo transfer; Exclusion criteria: Allergy to herbal medicines and specifically Nigella Sativa

Intervention groups

Intervention group: In this group, patients are prescribed one Nigella Sativa capsule each night in the first 7 days of menstruation and then one in the morning and one at night until the endometrium is ready; Control group: In this group, patients are prescribed estradiol 2mg tablets with a dose of 4 mg in the first 7 days of menstruation and then with a dose 6 mg until the endometrium is ready

Main outcome variables

Endometrial thickness, fertility rate, implantation, clinical and subclinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033085N5**

Registration date: **2021-03-23, 1400/01/03**

Registration timing: **prospective**

Last update: **2021-03-23, 1400/01/03**

Update count: **0**

Registration date

2021-03-23, 1400/01/03

Registrant information

Name

malihe afiat

Name of organization / entity

Mashhad medical school

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

afiatm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-09-19, 1400/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nigella Sativa capsules in order to prepare endometrium for frozen embryo transfer

Public title

Effect of Nigella Sativa capsules on preparation of

endometrium for frozen embryo transfer cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women between 20 and 42 years old with a frozen fetus who are candidate for embryo transfer

Exclusion criteria:

Allergy to herbal medicines and specifically Nigella Sativa

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single blinded clinical trial. Based on the random codes generated, participants are assigned to one of these two groups. Participants are not aware of the type of grouping and received treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.599

Health conditions studied

1

Description of health condition studied

Decreased or lack of fertility in a woman of childbearing age

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Third, tenth, twelfth, and fourteenth day of the cycle

Method of measurement

Transvaginal ultrasound

2

Description

Fertility rate

Timepoint

Two weeks after embryo transfer

Method of measurement

Beta HCG test

3

Description

Implantation rate

Timepoint

35 days after embryo transfer and 7 days after a positive result on pregnancy test

Method of measurement

Transvaginal ultrasound

4

Description

Subclinical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

Beta HCG test

5

Description

Clinical pregnancy

Timepoint

42 days after embryo transfer

Method of measurement

Transvaginal ultrasound

Secondary outcomes**1****Description**

live birth rate

Timepoint

after delivery

Method of measurement

live fetus delivery after 28 weeks of gestational age

Intervention groups**1****Description**

Intervention group: In this group, patients are prescribed one Nigella Sativa capsule each night in the first 7 days of menstruation and then one in the morning and one at night until the endometrium is ready.

Category

Treatment - Drugs

2**Description**

Control group: In this group, patients are prescribed estradiol 2mg tablets with a dose of 4 mg in the first 7 days of menstruation and then with a dose 6 mg until the endometrium is ready.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Milad Fertility Clinic

Full name of responsible person

Dr. Malihe Afiat

Street address

Milad Fertility Clinic, East Razi Street, Mashhad, Razavi Khorasan Province

City

Mashhad

Province

Razavi Khorasan

Postal code

9135913556

Phone

+98 51 3853 4021

Email

afiatm@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Razavi Khorasan

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9177899191

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+98 51 3841 2081

Email

ramresearch@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Malihe Afiat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

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Province

Razavi Khorasan

Postal code

9137913316

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+98 51 3802 2406

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afiatm@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Malihe Afiat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Carrying out analysis on data is permitted.

Comments