Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+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
City
Mashhad
Province
Razavi Khorasan
Postal code

9137913316
Phone
+98 51 3802 2406
Email
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
Gynecology and Obstetrics
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Postal code
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Phone
+98 51 3802 2406
Email
afiatm@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Malihe Afiat
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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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