Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of use Nigella sativa (black seed) capsules on the breastfeeding pattern of women

Protocol summary

Study aim

Determining the effect of black seed capsules on the breastfeeding pattern of women referring to Ayatollah Kashani Hospital, Jiroft 1403

Design

A clinical trial with a control group, with parallel groups, three blinded, randomized, phase 3 on 90 women. Createa blocked randomization list computer program was used for randomization.

Settings and conduct

ampling available at Ayatollah Kashani Hospital, Jiroft Randomization with the randomization site The capsules will be similar to each other and will be packed in similar envelopes, and code A or B will be written on each envelope, and the participants, researchers, and statistical analysts will not know the type of capsules. Participants take the capsules three times a day after breakfast, lunch and dinner for 12 days starting on the third day after birth. The telephone check list will be completed by the researcher on the fifth, tenth and fifteenth days of the birthday.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mothers aged 18-45, full-term and singleton babies, baby weight between 2500-4000 grams, mother's body mass index greater than or equal to 18.5 kg/m2, low-risk pregnancy Exclusion criteria: anatomical problems of the baby, receipt of herbal or chemical milk-enhancing drugs by the mother before the start of the study, mental illness, liver disease, cancer and thyroid gland, and levothyroxine use.

Intervention groups

The intervention group will be given a black seed capsule containing 250 mg of black seed powder, and the control group will be given a placebo containing 250 mg of cellulose compounds.

Main outcome variables

Exclusive breast feeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240609062066N1**
Registration date: **2024-08-31, 1403/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-31, 1403/06/10**
Update count: **0**

Registration date

2024-08-31, 1403/06/10

Registrant information

Name

niloofar shafipoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4321 7322

Email address

shafipoorniloofar024@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-20, 1403/05/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of use Nigella sativa (black seed) capsules on the breastfeeding pattern of women

Public title
the effect of Nigella sativa (black seed) capsules on the breastfeeding pattern of women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers aged 18-45 Full-term and single-term babies The baby's weight is between 2500-4000 grams The ability to suck the breast Low risk pregnancy The mother's body mass index is greater than or equal to 18.5 kg/m2 Desire to breastfeed
Exclusion criteria:
Anatomical problems of the newborn Abnormal maternal bleeding after delivery Receiving herbal or chemical milk-enhancing drug by the mother before starting the study Mental illness Liver disease and cancer Thyroid disease and levothyroxine use
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
First, a random sequence with a size of 4 will be created using the random blocking method on the web (using the computer program Createa blocked randomisation list with the link https://www.sealedenvelope.com/simple-randomiser/v1/lists). The method of concealment is by using non-transparent sealed envelopes. In this way, a random sequence is first created using the mentioned method, then 90 envelopes are prepared and each of the random sequences is on a registration card. and the cards are placed in the mail envelopes in order after the start of sampling based on the entry criteria, one of the mail envelopes is opened in order and the participant group is revealed and this procedure continues until the end of the sampling.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Black seed capsules and placebo will not have any difference in appearance. The envelopes of the intervention group with black capsules will be prepared with the same packaging as the envelopes of the control group, and code A or B will be written on the envelopes
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences
Street address
Research and Technology Vice-Chancellor, Building No. 3, Central Organization of Rafsanjan University of Medical Sciences,Imam Ali Blvd.Rafsanjan,
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2024-07-30, 1403/05/09
Ethics committee reference number
IR.RUMS.REC.1403.065

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Feeding babies with breast milk (number of babies fed with breast milk)
Timepoint
On the fifth, tenth and fifteenth day of birth
Method of measurement
During the researcher's phone call with the participants and asking how to feed the baby and completing the phone checklist

2

Description
Feeding babies with breast milk plus liquids except formula (number of babies fed with breast milk plus liquids except formula)

Timepoint
On the fifth, tenth and fifteenth day of birth
Method of measurement
During the researcher's phone call with the participants and asking how to feed the baby and completing the phone checklist

3

Description
Feeding babies with breast milk plus formula (number of babies fed with breast milk plus formula)
Timepoint
On the fifth, tenth and fifteenth day of birth
Method of measurement
During the researcher's phone call with the participants and asking how to feed the baby and completing the phone checklist

4

Description
Feeding babies with formula (number of babies fed with formula)
Timepoint
On the fifth, tenth and fifteenth day of birth
Method of measurement
During the researcher's phone call with the participants and asking how to feed the baby and completing the phone checklist

Secondary outcomes

1

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Intervention group: Black seed powder is prepared in the form of capsules containing 250 mg of black seed powder by Barij Essence Company, and the capsules are used three times a day after breakfast, lunch and dinner for 12 days from the third day of birth.
Category
Treatment - Drugs

2

Description
Control group: The ingredient used is cellulose compounds, which are prepared in the form of 250 mg capsules by Barij Essence Company, and the capsules are used three times a day after breakfast, lunch and dinner for 12 days from the third day of birth.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Jiroft Hospital
Full name of responsible person
Niloofar Shafipoor
Street address
left side, second door, North Keshavarzi Alley 18, Keshavarzi Ave.
City
Jiroft
Province
Kerman
Postal code
7861954356
Phone
+98 34 4321 7322
Email
shafipoorniloofar024@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Reza Vazirinejad
Street address
Enghelab Square
City
Rafsanjan
Province
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Postal code
7717933777
Phone
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Fax
+98 34 3428 0097
Email
rvazirinejad@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Niloofar Shafipoor
Position
Non-faculty
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
left side, second door, North Keshavarzi Alley 18, Keshavarzi Ave.
City
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Province
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Postal code
7861954356
Phone
+98 34 4321 7322
Email
shafipoorniloofar024@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Niloofar Shafipoor
Position
Non-faculty
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Niloofar Shafipoor
Position
Non-faculty
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 1 month after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions as well as to people who are also engaged in industry and can apply to receive them.
Under which criteria data/document could be used
There are no other conditions
From where data/document is obtainable
Niloofar Shafipoor Phone: 09011079452, 09932665020 Address: left side, second door, North Keshavarzi Alley 18, Keshavarzi Ave, Jiroft ,Kerman Gmail: shafipoorniloofar024@gmail.com Pouran Allahbakhshi Phone: 09138911459 Address: Faculty of Nursing and Midwifery, Parastar Ave, Rafsanjan, Kerman Rafsanjan University of Medical Sciences, Elkhebal Square, Kerman, Rafsanjan

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

E-mailing or calling the responsible people, answering immediately after receiving the e-mail or answering the phone call

Comments