Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Nigella Sativa oil on urinary incontinence and quality of life among menopausal women: a triple-blind randomized controlled trial

Protocol summary

Study aim
To determine the effect of Nigella Sativa oil on urinary incontinence and quality of life in menopausal women

Design
Clinical trial with a control group, with parallel groups, triple blinded, randomized with blocking method, phase three on 60 patients. The randomizer software will be used for randomization.

Settings and conduct
The study will be performed on 60 menopausal women who have a record in the health centers of Tabriz.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 45-60 age group; Passing one year from the last menstrual period after the onset of normal menopause; Not taking of drugs to treat urinary incontinence; Achieving a score of four and higher according to the first three questions and a score of six and higher according to the second three questions of the Questionnaire for Urinary Incontinence Diagnosis (QUID); Having a contact number to follow-up; Living in the city of Tabriz; Having a record in the health center. Exclusion criteria: Having a history of any physical or mental illness that causes urinary incontinence; Using other medications or traditional medicine to treat urinary incontinence; Presence of urinary tract infection; Allergy to Nigella Sativa

Intervention groups
The intervention group 1 or treatment group: This group will receive Nigella Sativa oil in the form of 2 to 3 drops below the navel on the abdomen and sides twice a day without massage for 8 weeks.; The intervention group 2 or control group: This group will receive placebo of Nigella Sativa oil in the form of 2 to 3 drops below the navel on the abdomen and sides twice a day without massage for 8 weeks.

Main outcome variables
Urinary incontinence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N67**
Registration date: **2021-06-08, 1400/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-08, 1400/03/18**
Update count: **0**

Registration date
2021-06-08, 1400/03/18

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-30, 1400/03/09

Expected recruitment end date
2021-09-20, 1400/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Nigella Sativa oil on urinary incontinence and quality of life among menopausal women: a triple-blind randomized controlled trial

Public title
The effect of Nigella Sativa oil on urinary incontinence and quality of life among menopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
45-60 age group Passing one year from the last menstrual period after the onset of normal menopause Not taking of drugs to treat urinary incontinence Achieving a score of four and higher according to the first three questions of the Questionnaire for Urinary Incontinence (QUID) Having a contact number to follow-up Living in the city of Tabriz Having a record in the health center (SIB system) Achieving a score of six and higher according to the second three questions of the QUID Not taking of tobacco and alcohol

Exclusion criteria:
Having a history of any physical or mental illness that causes urinary incontinence Using other medications or traditional medicine to treat urinary incontinence Presence of urinary tract infection Allergy to Nigella Sativa Using of biofeedback to treat urinary incontinence

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in the study will be assigned to two groups (one group receiving Nigella Sativa oil and one group receiving placebo oil with the same protocol) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1. To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer software, and the Nigella Sativa oil and placebo oil will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The participants, researcher and data analyst will be blinded in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2021-05-01, 1400/02/11

Ethics committee reference number
IR.TBZMED.REC.1400.104

Health conditions studied

1

Description of health condition studied
Urinary incontinence

ICD-10 code
N39.4

ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Urinary incontinence score

Timepoint
Before the intervention and 8 weeks after the start of consumption of Nigella Sativa oil

Method of measurement
Urine Incontinence Questionnaire

Secondary outcomes

1

Description
Score of urinary incontinence specific quality of life
Timepoint
Before the intervention and 8 weeks after the start of consumption of Nigella Sativa oil
Method of measurement
Incontinence Quality of Life Instrument

2

Description
Score of Menopause Specific Quality of Life
Timepoint
Before the intervention and 8 weeks after the start of consumption of Nigella Sativa oil
Method of measurement
Menopause Specific Quality of Life Questionnaire

3

Description
Sexual function score
Timepoint
Before the intervention and 8 weeks after the start of consumption of Nigella Sativa oil
Method of measurement
Female Sexual Function Index

4

Description
Level of satisfaction with the received intervention
Timepoint
8 weeks after the start of consumption of Nigella Sativa oil
Method of measurement
This variable will be measured using an item based on the Likert scale from very satisfied to very dissatisfied.

5

Description
Side events Including pain at the site of drug use, skin complications, increased heart rate, headache and other side events reported by the participant.
Timepoint
8 weeks after the start of consumption of Nigella Sativa oil and during the intervention through participants' report.
Method of measurement
This variable will be measured using a side events checklist designed by the researcher.

Intervention groups

1

Description
Intervention group will receive Nigella Sativa oil in the form of 2 to 3 drops under the navel on the abdomen and sides twice a day without massage for 8 weeks. The oil will be provided by Barij Essence Pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group will receive placebo oil in the form of 2 to 3 drops under the navel on the abdomen and sides twice a day without massage for 8 weeks. The placebo oil will be provided by Barij Essence Pharmaceutical company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Tabriz city
Full name of responsible person
Afsaneh Alizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Afsaneh Alizadeh
Position
student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participant data is confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available