Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of topical black seed oil on urinary incontinence in elderly women

Protocol summary

Study aim
Determining the effect of topical use of black seed oil on urinary incontinence in elderly women
Design
A randomized, parallel-controlled group clinical trial on 80 patients in 2021
Settings and conduct
First, convenience sampling method will be performed to select eligible elderly women with urinary incontinence, including stress, urge and mixed types, from mild to moderate urinary incontinence referred to the gynecology clinic of Imam Khomeini Hospital, Touba Clinic and health centers of Sari. After obtaining informed written consent from patients and obtaining approval from their medical practitioners, random assignment of samples to intervention and control groups will be performed. In the intervention group, 15 drops of black seed oil will be applied from the umbilicus to the pubic area for 6 weeks, twice a day (morning and night). In the control group, Firooz Body Oil for Baby will be applied in the same manner. The random allocation and the administration of black seed oil and placebo oil to the samples will be performed by the secretary. Researchers and patients will be unaware of their own assignment to one of the two intervention or control groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Normal cognitive status (obtaining a score of ≥7 based on cognitive assessment tools) 2- History of mild to moderate urinary incontinence (obtaining a score of 1 to 12) Exclusion criteria 1- No history of taking medication for urinary incontinence during the two weeks before the intervention 2- Absence of active urinary tract infection
Intervention groups
In the intervention group, 15 drops of black seed oil will be applied from the umbilicus to the pubic area for 6 weeks, twice a day (morning and night). In the control group, Firooz Body Oil for Baby will be applied in the same manner.
Main outcome variables
Urinary incontinence

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200118046170N3**
Registration date: **2021-06-29, 1400/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-29, 1400/04/08**
Update count: **0**
Registration date
2021-06-29, 1400/04/08

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-22, 1400/04/01
Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of topical black seed oil on urinary incontinence in elderly women

Public title
Effect of black seed oil on urinary incontinence
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Normal cognitive status (obtaining a score of ≥7 based on cognitive assessment tools) History of mild to moderate urinary incontinence (obtaining a score of 1 to 12) Informed consent
Exclusion criteria:
No history of taking medication for urinary incontinence during the two weeks before the intervention Absence of active urinary tract infection Absence of neurogenic disorders (multiple sclerosis, stroke and spinal cord injury) No history of pelvic surgery during the last year No bladder cancer Lack of hypersensitivity to vegetable oils Body mass index(BMI) less than 40 No history of skin disease in the sites of drug administration Absence of obsessive-compulsive disorder
Age
From **60 years** old to **80 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
• Permuted block randomization is designed to randomly assign participants to two intervention groups and the control group in equal numbers in each group using appropriate software. In this method, each block with a certain number is assigned to each group. Six possible combinations of group assignment (AABB, ABAB, BAAB, BABA, BBAA, ABBA) exist in quadruple blocks. Each time, the computer program randomly selects one of the scenarios and sets the order. For example, if the AABB mode is selected for the first time, the first and second persons will be in group A and the third and fourth persons will be in group B. Finally, the assignment of research units is determined in order for 80 samples. Thus, 80 opaque envelopes are prepared, which are numbered from 1 to 80. Based on computer results, the letter A or letter B is written inside each envelope. No one knows which group in the envelope belongs to. The secretary of the clinic opens the envelopes for the elderly in the order in which they visit, to place the people in their own designated group. Group A will be the intervention group and will receive the necessary interventions according to the protocol. The intervention in the control group is routine (using placebo). The evaluator is also unaware of the group assignment. .
Blinding (investigator's opinion)
Double blinded
Blinding description
The random allocation and the administration of black seed oil and placebo oil to the samples will be performed by the secretary. Researchers and patients will be unaware of their own assignment to one of the two intervention or control groups. The lid of Firooz Baby Oil container (Oil for placebo) is impregnated with black seed oil. Both containers of oil (placebo and black seed) are similar.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Moalem Square. Deputy of research and technology. Mazandaran University of Medical Sciences.
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Province
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4816715793
Approval date
2020-12-29, 1399/10/09
Ethics committee reference number
IR.MAZUMS.REC.1399.820

Health conditions studied

1

Description of health condition studied
Urinary incontinence
ICD-10 code
N39.46
ICD-10 code description
Mixed incontinence

Primary outcomes

1

Description
Urinary incontinence
Timepoint

Before the intervention, after the third and sixth weeks of the intervention

Method of measurement

The questionnaire contains 6 questions, the first 2 questions are related to demographic information, and the rest examines the frequency of urine leakage (score 0 to 5), the rate of urine leakage (score 0 to 6), the effect of urine leakage on quality of life (score 0 to 10) and the time of urine leakage. No score is considered for the last question (35). The total score of the questionnaire is 21, and is divided into mild (1-5), moderate (6-12), severe (13-18) and very severe (19-21).

Secondary outcomes

1

Description

Urinary incontinence

Timepoint

Third and sixth week

Method of measurement

The questionnaire

Intervention groups

1

Description

Intervention group: The intervention group will apply 15 drops of black seed oil from the umbilicus to the pubic area for 6 weeks, twice a day (morning and night). Black seed oil will be prepared from Barij Essence Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: The control group will apply 15 drops of Firooz Body Oil for Baby from the umbilicus to the pubic area for 6 weeks, twice a day (morning and night). Body oil will be prepared from Firooz Hygienic Group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba Clinic in Sari

Full name of responsible person

Ali Mohammadi

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Recruitment center

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Recruitment center

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Sponsors / Funding sources

1

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Grant name
Mazandaran University of Medical Sciences_____
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available