

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Manizheh zakizad

Name of organization / entity

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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.

City

Sari

Province

Mazandaran

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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

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2

Recruitment center

Name of recruitment center

Sari Imam Khomeini Hospital Clinic

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Health Center No. 12

Full name of responsible person

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Recruitment center

Name of recruitment center

Health Center No. 13

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Manizheh Zakizad Abkenar

Position

Assistant Professor, Health Education and Health
Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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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