Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Pilot study, the effect of fennelis syrup on hot flashes in postmenopausal women

Protocol summary

Study aim
Investigating the effectiveness of fenelis syrup on hot flashes in postmenopausal women
Design
Clinical trial on 10 patients (pilot study)
Settings and conduct
Postmenopausal patients referred to Shariat Panahi Health Center, Shahid Beheshti School of Traditional Medicine after initial examinations and physician's opinion and if the patient wishes, were included in the study and treated with fenelis syrup for 1 month (twice a day, morning and night, each time 10 cc), the degree of hot flashes before the treatment, during treatment, and after treatment will be assessed by a questionnaire.
Participants/Inclusion and exclusion criteria
Menopausal women with hot flashes without a history of malignancy and removing the uterus and ovaries
Intervention groups
Postmenopausal women with a history of hot flashes without a history of malignancy and remove the uterus and ovaries referred to Shariat Panahi Health Center who wish to be treated with herbal medicines. Patients will be treated with fenelis syrup for 1 month (twice a day, morning and night, each time 10 cc)
Main outcome variables
"menopausal hot flashes"

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200112046087N4**
Registration date: **2020-09-28, 1399/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-28, 1399/07/07**
Update count: **0**

Registration date
2020-09-28, 1399/07/07

Registrant information
Name
Hanieh Babaei
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2021-01-20, 1399/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Pilot study, the effect of fennelis syrup on hot flashes in postmenopausal women

Public title
Evaluation of the effectiveness of fennelis syrup on hot flashes in postmenopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Complaining of hot flashes Menopause Absence of menstruation during the last 12 months without

removing the uterus and ovaries

Exclusion criteria:

Malignancy Taking anticoagulants drugs History of any cardiovascular disease, diabetes, hypertension, neurological disease and cancer Self-medication for hot flashes such as clonidine, methyl dopa, bellegal

Age

From **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical sciences, Daneshju Blv.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-01-26, 1398/11/06

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.697

Health conditions studied

1

Description of health condition studied

Hot flashes

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Hot flashes in postmenopausal women (severity and duration of hot flashes)

Timepoint

Prior to the intervention, during the intervention and 4 weeks after the intervention

Method of measurement

Hot flashes questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: women with hot flashes referred to the clinic. Patients consume 10 cc of syrup made twice a day, morning and night, each time, which has been formulated and quality controlled in the Research Center for Traditional Medicine and Medical Content. (Fenelis syrup contains one to one ratio of fennel seeds and chopped lemongrass leaves)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Faculty of Traditional Medicine (Shariat Panahi Health School)

Full name of responsible person

Mojgan Tansaz

Street address

No. 8, Shams Alley, Vali-e Asr Ave, The Faculty of Traditional Medicine of Shahid Beheshti University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti Faculty of Traditional Medicine
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojgan Tansaz
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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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
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
Title and more details about the data/document
Data will be sent by researchers upon request.
When the data will become available and for how long
After printing the study results
To whom data/document is available
researchers
Under which criteria data/document could be used
For systematic review studies or meta-analysis
From where data/document is obtainable
Dr. Mojgan Tansaz tansaz_mojgan@yahoo.com
What processes are involved for a request to access data/document
Correspondence by email with the executor
Comments