

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Effect of addition of saffron to vitamin E on the sexual function in women of reproductive age with sexual dysfunction: a randomized controlled trial

Protocol summary

Study aim

The effect of addition of saffron to vitamin E on sexual function of women of reproductive age with sexual dysfunction

Design

Randomized superiority placebo-controlled double blind trial with two parallel arms: 50 participants will be allocated into the groups using stratified block randomization.

Settings and conduct

Eligible women covered by selected health centers in Tabriz will be recognized through the SIB system and invited to participate into the trial. After obtaining informed written consent and baseline data, they will be randomly assigned to the intervention or control groups. Sequence generation and preparation of drug packages will be performed by a person not involved in data collection. The participants, investigators, care providers, and outcome assessors will be blinded.

Participants/Inclusion and exclusion criteria

Participants will be literate married women aged 15-49 years who have sexual dysfunction with no sleep disorder. Exclusion criteria are: sexually inactive, obvious sexual dysfunction of husband, pregnancy, breastfeeding in the first six months after delivery, no use of an effective contraceptive method, willing to get pregnant in near future, drug or alcohol addiction, sensitivity to saffron, severe depression or other known psychological disorders, drug treatment for sexual dysfunction, underlying serious diseases, Use of drugs that affect one's sexual response, menopause, daily consumption of saffron and/or vitamin E supplement, participation in another trial.

Intervention groups

For 8 weeks, each day intervention group will get one saffrotine capsule (15 mg saffron) and one saffrodid capsule (15 mg saffron+ 50 mg vitamin E), and control

group a placebo capsule (saffrotine-like) and a 50 mg vitamin E capsule (saffrodid-like); produced by Green Plants of life Company.

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N36**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 2699

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of addition of saffron to vitamin E on the sexual function in women of reproductive age with sexual dysfunction: a randomized controlled trial

Public title

Effect of addition of saffron to vitamin E on the sexual function in women of reproductive age

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Literacy (to be able to fill out the questionnaires) Married women aged 15 to 49 years Sexual dysfunction (FSFI score of less than 28) Sexually active No sleep disorder (score 5 or less in Pittsburgh Sleep Quality Index)

Exclusion criteria:

Drug and alcohol addiction Known sensitivity to saffron Pregnancy The first six months after delivery in lactating women Severe depression or any other known psychological disorder Occurrence of any serious stressors (such as separation of parents, death of a first-degree relative) in the last 3 months Underlying diseases (heart, digestive, respiratory, epilepsy, hypertension, diabetes) according to self report Regular use of any drugs affecting one's sexual response (including anti hypertensive drugs, thiazide diuretics, antidepressants, antihistamines, barbiturates, narcotics, diazepam, amphetamines, cocaine, herbal remedies) Menopause Daily consumption of saffron Daily intake of vitamin E supplements Participation in another trial Obvious sexual dysfunction in husband (according to woman report) No use of an effective contraceptive method Willing to become pregnant in near future

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated into intervention or control groups using stratified (two strata; with moderate depressive symptoms or with no or mild depressive

symptoms) block randomization with block size of 4 and allocation ratio of 1: 1. Allocation sequence will be determined using a computerized program (randomizer). To conceal the allocation, we will use sequentially numbered identical drug containers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The saffron, saffron and placebo capsules will look quite similar, quite similar. Sequence allocation and preparation of drug packages will be performed by a non-involved person in sampling and data collection. The researcher, data collector, and analyzer will not be aware of the type of intervention received.

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

Third floor, Second central building, Golgasht street

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Tabriz

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East Azarbaijan

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5165665931

Approval date

2020-05-04, 1399/02/15

Ethics committee reference number

IR.TBZMED.REC.1399.120

Health conditions studied**1****Description of health condition studied**

Sexual dysfunction

ICD-10 code

F52.22

ICD-10 code description

Female sexual arousal disorder

Primary outcomes**1****Description**

Sexual function Score

Timepoint

At baseline, 4 and 8 weeks of intervention and 4 weeks after intervention

Method of measurement

Female sexual function questionnaire (FSFI)

Secondary outcomes

1

Description

Anxiety

Timepoint

At baseline, 4 and 8 weeks of intervention and 4 weeks after intervention

Method of measurement

Depression, Anxiety and Stress Scale (DASS-21)

2

Description

Depression

Timepoint

At baseline, 4 and 8 weeks of intervention and 4 weeks after intervention

Method of measurement

Depression, Anxiety and Stress Scale (DASS-21)

3

Description

Stress

Timepoint

At baseline, 4 and 8 weeks of intervention and 4 weeks after intervention

Method of measurement

Depression, Anxiety and Stress Scale (DASS-21)

Intervention groups

1

Description

Intervention group: For 8 weeks, each day one saffrotine capsule (15 mg saffron) and one saffradid capsule (15 mg saffron+ 50 mg vitamin E), produced by Green Plants of life Company.

Category

Treatment - Drugs

2

Description

Control group: For 8 weeks, each day one oral placebo capsule (identical with saffrotine in terms of appearance, smell and taste) and a 50 mg vitamin E capsule (identical with saffradid in terms of appearance, smell and taste); produced by Green Plants of life Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Public Health Centers

Full name of responsible person

Dr Ali Ebadi

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Sponsors / Funding sources

1

Sponsor

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Web page address

<http://researchvice.tbzmed.ac.ir>

Grant name

Special Grant for 20% active researchers in the University

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

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

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

All deidentified IPD can be shared.

When the data will become available and for how long

Starting just after publication

To whom data/document is available

Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief editor of the journals for checking.

From where data/document is obtainable

Refer to the email address. (alizades@tbzmed.ac.ir)
What processes are involved for a request to access data/document

Requests will be sent by email and data will be available within two weeks.
Comments