Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Feb 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 (safrotine-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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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, diazepines, 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 safrotine, safrodide 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 centralbuilding, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
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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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

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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Position
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Person responsible for updating data

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alizades@tbzmed.ac.ir

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