Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

The Effect of Topical Product of Saffron (Crocus sativus L.) on Erectile Dysfunction in Men with Diabetes: A Randomized Double Blind Placebo-controlled Trial

Protocol summary

Summary

Objectives: Assessing the effect of topical Saffron (Crocus sativus L.) product on erectile dysfunction in diabetic men. Design: A double blind (blinding investigators and participants) controlled clinical trial with parallel allocation in two groups of experimental (n=25 patients) and placebo (n=25 patients). Setting and Conduct: Married diabetic males with erectile dysfunction referring to traditional medicine clinic of Mashhad University of Medical Sciences in 1393. Participants Including Major Eligibility Criteria: Inclusion Criterion: Married diabetic men with erectile dysfunction. Exclusion Criteria: A) Patients with psychological disorders and B) Patients with central neurologic disorders. Intervention: A) Experimental Group: Applying 0.5 g of topical Saffron product on penis before intercourse, B) Control Group: Applying 0.5 g of placebo on the penis before intercourse. Major Outcome Measures: Primary outcome measure: Erectile Function, and secondary outcome measures: A) Orgasmic Function, B) Sexual Desire, and C) Intercourse Satisfaction which will be assessed using the Farsi version of the International Index of Erectile Function (IIEF-15) scale before the intervention and 4 weeks after in the experimental and control groups.

General information

Acronym

N/A

IRCT registration information

IRCT registration number: **IRCT2014040717169N1**
Registration date: **2014-06-14, 1393/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-14, 1393/03/24

Registrant information

Name

Hossein Mohammadzadeh Moghaddam

Name of organization / entity

Traditional Medicine Faculty, Mashhad University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 51 1855 2188

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Topical Product of Saffron (Crocus sativus L.) on Erectile Dysfunction in Men with Diabetes: A Randomized Double Blind Placebo-controlled Trial

Public title

The Effect of Topical Saffron Product on Erectile

Dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criterion: Married diabetic men with erectile dysfunction. Exclusion Criteria: A) Patients with psychological disorders and B) Patients with central neurologic disorders.

Age
From **20 years** old to **80 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization method is Simple Randomization using Fleiss table. Double blinding (blinding investigators and participants) was used to reduce the information bias.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Ghorayshi Building, Daneshgah Street,

City
Mashhad,

Postal code
91375345

Approval date
2014-02-22, 1392/12/03

Ethics committee reference number
921988

Health conditions studied

1

Description of health condition studied
Erectile Dysfunction

ICD-10 code
N48/4

ICD-10 code description
Impotence of Organic Origin

Primary outcomes

1

Description
Erectile Function

Timepoint
Before Intervention and One Month after Intervention

Method of measurement
Farsi Version of International Index of Erectile Function (IIEF-15)

Secondary outcomes

1

Description
Orgasmic Function

Timepoint
Before Intervention and One Month after Intervention

Method of measurement
Farsi Version of International Index of Erectile Function (IIEF-15)

2

Description
Sexual Desire

Timepoint
Before Intervention and One Month after Intervention

Method of measurement
Farsi Version of International Index of Erectile Function (IIEF-15)

3

Description
Intercourse Satisfaction

Timepoint
Before Intervention and One Month after Intervention

Method of measurement
Farsi Version of International Index of Erectile Function (IIEF-15)

Intervention groups

1

Description
Experimental Group: Rubbing Topical Saffron Product on the Penis before Intercourse

Category
Treatment - Drugs

2

Description
Control Group: Rubbing the Placebo on the Penis before Intercourse.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional Medicine Faculty Clinic, Mashhad University of Medical Sciences
Full name of responsible person
Doctor Seyed Mohammad Nazari
Street address
Next to Sina Hospital, Jahad No. 6 Steet,
City
Mashhad,

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences
Full name of responsible person
Doctor Mohsen Tafaghodi
Street address
Ghorayshi Building, Daneshgah Street,
City
Mashhad,
Grant name
دکتر سید محمد نظری
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Traditional Medicine Faculty, Mashhad University of Medical Sciences
Full name of responsible person
Doctor Hossein Mohammadzadeh Moghaddam
Position
PhD Candidate in Traditional Iranian Medicine
Other areas of specialty/work
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Mashhad University of Medical Sciences
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Doctor Ali Shamsa
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Professor and Urologist, Renal Transplantation Fellowship,
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Person responsible for updating data

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Name of organization / entity
Traditional Medicine Faculty, Mashhad University of Medical Sciences
Full name of responsible person
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PhD Candidate in Traditional Iranian Medicine
Other areas of specialty/work
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Web page address
www.mums.ac.ir/tim

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty