

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

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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,

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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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Person responsible for scientific inquiries

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Name of organization / entity

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Doctor Ali Shamsa

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Professor and Urologist, Renal Transplantation Fellowship,

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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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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*