

# 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

+98 51 1855 2188

###### Email address

homm1349@gmail.com

##### 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

#### Street address

Next to Sina Hospital, Jahad No. 6 Street,

#### City

Mashhad,

#### Postal code

9135913556

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+98 51 1855 2189

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#### Email

homm1349@gmail.com

#### Web page address

www.mums.ac.ir/tim

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Doctor Ali Shamsa

#### Position

Professor and Urologist, Renal Transplantation Fellowship,

#### Other areas of specialty/work

#### Street address

Imam Reza Hospital,

#### City

Mashhad,

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+98 51 1854 4799

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shamsaa@mums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Traditional Medicine Faculty, Mashhad University of Medical Sciences

#### Full name of responsible person

Doctor Hossein Mohammadzadeh Moghaddam

#### Position

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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*