

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of saffron on erectile dysfunction in men

#### Protocol summary

##### Study aim

Determining the effect of saffron capsules on erectile dysfunction in men

##### Design

The present study is a clinical trial study with a control group and an intervention group that will be performed in parallel, without blinding, randomly on 24 men.

##### Settings and conduct

The study population: All men working at industrial towns of Larestan city

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Do not use alternative therapies such as hormone therapy; Having informed consent to participate in research; Ability to swallow and no oral and digestive problems; Candidates should not participate in other treatment programs that interfere with the present study. Non-inclusion criteria: Unwillingness of samples to participate in research; History of allergy to herbal medicines; Addiction to drugs, alcohol and painkillers; Consumption of psychiatric drugs; Having severe depression or anxiety

##### Intervention groups

Intervention group: daily intake of 2 capsules of 15 mg of saffron twice for 4 weeks. Control group: No special treatment

##### Main outcome variables

The International Index of Erectile Function score

#### General information

##### Reason for update

Prolong the sampling process

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090304001742N9**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**

Update count: **2**

##### Registration date

2021-05-31, 1400/03/10

##### Registrant information

###### Name

mohammadrafi bazrafshan

###### Name of organization / entity

shiraz university medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 917 382 1959

###### Email address

mrbazr@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-01, 1400/03/11

##### Expected recruitment end date

2021-07-01, 1400/04/10

##### Actual recruitment start date

2021-06-01, 1400/03/11

##### Actual recruitment end date

2021-09-30, 1400/07/08

##### Trial completion date

2021-12-28, 1400/10/07

##### Scientific title

The effect of saffron on erectile dysfunction in men

##### Public title

The effect of saffron on erectile dysfunction in men

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age over 18 years Do not use alternative therapies such as hormone therapy Having informed consent to participate in research Ability to swallow No oral or digestive problems Not participating in other treatment

programs that interfere with the present study

**Exclusion criteria:**

History of allergy to herbal medicines Addiction to drugs and alcohol and painkillers Taking psychiatric drugs

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

Actual sample size reached: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, the list of industrial companies of Larestan city is written on paper, in the next step, the name of each center put in a separate envelope and one of the envelopes is selected at random. The researcher sampling men by referring to the selected industrial company using available sampling and applying the conditions for inclusion and non-inclusion the study. The samples allocated to intervention and control groups according to the block randomization. Thus, according to the sample size of this study, which is estimated to be 24 people, 4 blocks with 6 columns are used. Therefore, at the end, 12 people are placed in each group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Larestan University of Medical Sciences

**Street address**

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City

**City**

Larestan

**Province**

Fars

**Postal code**

7431889629

**Approval date**

2021-03-01, 1399/12/11

**Ethics committee reference number**

IR.LARUMS.REC.1399.016

**Health conditions studied**

1

**Description of health condition studied**

Erectile dysfunction in men

**ICD-10 code**

F52

**ICD-10 code description**

Sexual dysfunction not due to a substance or known physiological condition

**Primary outcomes**

1

**Description**

The International Index of Erectile Function score

**Timepoint**

Before the intervention and immediately after the intervention

**Method of measurement**

The International Index of Erectile Function

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: The intervention includes daily intake of 2 15-mg capsules of saffron twice a day for 4 weeks.

**Category**

Treatment - Drugs

2

**Description**

Control group: The control group does not receive any treatment.

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Larestan industrial companies

**Full name of responsible person**

Dr. Mohammad-Rafi Bazrafshan

**Street address**

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan

St., North Ghadir Blvd., New City  
**City**  
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+98 71 5224 7110  
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+98 71 5224 7111  
**Email**  
m.bazrafshan@larums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Dr Behzad Rezaei

**Street address**

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county

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**Phone**

+98 71 5225 5512

**Email**

m.bazrafshan@larums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Larestan 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**

Larestan University of Medical Sciences

**Full name of responsible person**

Mohammad-Rafi Bazrafshan

**Position**

دانشیار

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Behzad Rezaei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Email**

m.bazrafshan@larums.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Mohammad-Rafi Bazrafshan

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Email**

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Participants' information can be shared after it becomes unrecognizable

**When the data will become available and for how long**

Access begins a year after the publication of results

**To whom data/document is available**

People who are working in the academic and scientific institutions

**Under which criteria data/document could be used**

It needs the agreement of Larestan University of Medical Sciences

**From where data/document is obtainable**

Dr. Mohammad Rafi Bazrafshan, Associate Professor, Larestan School of Medical Sciences, Email: m.bazrafshan@larums.ac.ir, Contact Phone: 07152247110, Mobile Number: 09173821959

**What processes are involved for a request to access data/document**

Written and formal request to the vice chancellor for research of Larestan University of Medical Sciences

**Comments**