

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

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7431895639
Phone
+98 71 5224 7110
Fax
+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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Larestan

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Postal code

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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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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