

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of capsule containing Tribulus Terrestris, Zingiber Officinale extracts and L-arginine on libido of low libido men

#### Protocol summary

##### Summary

this double-blind clinical trial will be discussed about effectiveness of herbal capsules containing extracts of Tribulus terrestris, ginger and L-arginine on sexual desire. Based on personal complaints, 60 males 30 to 70 years old with decreased sexual desire and who do not underlying condition contain physical and mental disease that need treat ,randomly divided into, two groups receiving placebo capsules or herbal capsules twice-daily for 6 weeks. At the beginning and end of the study individual Visited and at the end of third week will be followed by telephone about the continuation of cooperation, possible side effects and exclusion criteria .The level of testosterone, anti-oxidants, Hullbert Index of Sexual Desire and libido (VAS) will be specified in the beginning and end of study and Changes will be calculated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015122012438N14**

Registration date: **2016-01-09, 1394/10/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-01-09, 1394/10/19

##### Registrant information

##### Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij research center of medicinal plants

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of capsule containing Tribulus Terrestris, Zingiber Officinale extracts and L-arginine on libido of low libido men

##### Public title

The effect of capsule containing Tribulus Terrestris, Zingiber Officinale extracts and L-arginine on male libido

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients between 30 and 70 years old with decreased sexual desire based on personal complaints Exclusion criteria: internal medicine,use medicine affecting sexual performance Addiction and smoking,alcohol Psychiatric disease and family problems Use herbal medicine that affect on sexual desire Physical and Psychiatric disease wife, other Sexual dysfunction multi partner Known sensitivity to medicinal herbal used in the study Any psychological counseling during the study period

**Age**

From **30 years** old to **70 years** old

**Gender**

Male

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

**Street address**

Kashan University Of Medical Sciences, Kashan

**City**

Kashan

**Postal code****Approval date**

2015-11-24, 1394/09/03

**Ethics committee reference number**

ir.kaums.rec1394.93181122

**Health conditions studied****1****Description of health condition studied**

loss of sexual desire

**ICD-10 code**

F52.0

**ICD-10 code description**

Lack or loss of sexual desire

**Primary outcomes****1****Description**

Hullbert Index of Sexual Desire

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

questionnaire

**2****Description**

Libido

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

VAS

**3****Description**

TAC

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

blood sample

**4****Description**

Testosterone

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

blood sample

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention:herbal capsule-two times a day for 6 weeks

**Category**

Treatment - Drugs

**2****Description**

control:placebo capsule-two times a day for 6 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kargarnejad Hospital in Kashan, Kashan

**Full name of responsible person**

Dr Mohsen Taghizadeh

**Street address****City**

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Barij Research Center of Medicinal Herbs

**Full name of responsible person**

Miss L.Hejazi

**Street address**

Km. 44 of Kashan - Delijan Rd, Mashhad-e- Ardehal

Kashan

**City**

Kashan

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

Yes

**Title of funding source**

Barij Research Center of Medicinal Herbs

**Proportion provided by this source****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*

### 2

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Kashan University of Medical Science

**Full name of responsible person**

Dr Gholam Ali Hamidi

**Street address**

Kashan university of Medical Science, Kashan

**City**

Kashan

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

Yes

**Title of funding source**

Vice chancellor for research of Kashan University of Medical Science

**Proportion provided by this source****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**

Kashan University of Medical Sciences

**Full name of responsible person**

Mohsen Taghizadeh

**Position**

PHD

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Web page address****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*