

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Efficacy of Tribulus Teresteris in female sexual disorder in reproductive ages

#### Protocol summary

##### Summary

**Aim:** Evaluation of efficacy of Tribulus terresteris on sexual response in women with reduced libido **Design:** Reduced libido is a complaint of 30-50% in women. Despite its high prevalence, there are not enough studies about its management. Aside from hormonal therapy, there are no current FDA approved medical treatments for reduced libido in female patients. **Setting and conduct:** Many herbal remedies have been used for reduced libido in women in the Iranian traditional medicine practice including Tribulus terresteris. Our study will evaluate this herbal remedy in such group of patients. **Participants:** Inclusion criteria: Women with reduced libido; without any serious disease; with a recent normal pap smear (it could be three months old); and normal vaginal and breast physical examination are the choice. Exclusion criteria: If the sexual partner is present less than half of the month; past medical history of breast or genital cancer and under therapy for depression or other physical or mental disorders. **Intervention:** This is a double blind study comparing the herbal remedy with the placebo. The sample size is 60 women, who undergo an interview in the beginning of the study to confirm their reduced libido according with DSM4 criteria. **Measures:** Subsequently they fill FSFI (Female Sexual Function Index) questionnaire and receive the herbal remedy. The subjects will be seen 2 and 6 weeks after being on therapy. They fill the same questionnaire after being on treatment for 6 weeks. FSFI questionnaire evaluate five elements: desire, arousal, satisfaction, orgasm and dyspareunia. This study evaluate the effect of our herbal remedy Tribulus terresteris, on those five elements.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012111111425N1**

Registration date: **2012-12-03, 1391/09/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-12-03, 1391/09/13

##### Registrant information

###### Name

Elham Akhtari

###### Name of organization / entity

Tehran University of Medical Colledge

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2610 1305

###### Email address

e-akhtari@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medicine

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2014-06-22, 1393/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Tribulus Terresteris in female sexual disorder in reproductive ages

## Public title

Efficacy and safety of Tribulus terrestris in female sexual disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Fixed partner; Persistent or intermittent low libido; A normal pelvic examination; A normal pap smear; A normal breast examination.

Exclusion criteria: No fixed partner; A serious medical situation; History of genital or breast cancer; An under observed depression or other psychological disorders

## Age

From **15 years** old to **45 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single 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 traditional medicine university of Tehran medical college

##### Street address

Islamic medicinal research institute, Pirnia Ave., Lalehzar St., Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2012-11-12, 1391/08/22

#### Ethics committee reference number

847/26/پ/ط/م

## Health conditions studied

### 1

#### Description of health condition studied

Female sexual disease

#### ICD-10 code

F-52

#### ICD-10 code description

Sexual dysfunction not caused by organic disorder or disease

## Primary outcomes

### 1

#### Description

libido

#### Timepoint

At the beginning of the trial, 7th day and one month after end of the drug

#### Method of measurement

FSFI questionnaire

## Secondary outcomes

### 1

#### Description

arousal

#### Timepoint

At the beginning of the study, 7 days after starting the drug and one month after finishing the drug

#### Method of measurement

FSFI questionnaire

### 2

#### Description

Desire

#### Timepoint

In the beginning of study, 7 days after it and 1 month after finishing the drug

#### Method of measurement

FSFI questionnaire

### 3

#### Description

Satisfaction

#### Timepoint

At the beginning of the study, 7 days after it and 1 month after finishing the drug

#### Method of measurement

FSFI questionnaire

### 4

#### Description

Orgasm

#### Timepoint

At the beginning of the study, 7 days after it and 1 month after finishing the drug

#### Method of measurement

FSFI questionnaire

## 5

### Description

Dysparonia

### Timepoint

At the beginning of the study, 7 days after it and 1 month after finishing the drug

### Method of measurement

FSFI questionnaire

## Intervention groups

### 1

#### Description

In the drug group: a syrup from Tribulus extract, 7.5 cc, twice a day for 1 week

#### Category

Treatment - Drugs

### 2

#### Description

In control group: A placebo syrup, 7.5 cc, twice a day, for 1 week

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital

##### Full name of responsible person

Akhtari Elham

##### Street address

Behesht Ave., Vahdat e Eslami ST., Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica

##### Full name of responsible person

Dr. Minaei

##### Street address

Behesht Street, Vahdat eslami Ave.

##### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica

##### 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 of Tehran Medical Colledge

#### Full name of responsible person

Elham Akhtari

#### Position

PHD coarse

#### Other areas of specialty/work

#### Street address

Behesht Ave., Vahdat eslami St.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Traditional Medicine of Tehran Medical Colledge

#### Full name of responsible person

Dr. Mansoor Keshavarz

#### Position

Associated professor

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Traditional medicine of Tehran medical college

**Full name of responsible person**

Elham Akhtari

**Position**

PHD student

**Other areas of specialty/work****Street address**

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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*