Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of Tribulus Teresteris in female sexual disorder in reproductive ages

Protocol summary

Summary

Aim: Evaluation of efficacy of Tribulus teresteris 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 teresteris. 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 coab 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 ot 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 dysparonia. This study evaluate the effect of our herbal remedy Tribulus teresteris, 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

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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 Teresteris in female sexual disorder in reproductive ages

Public title
Efficacy and safety of Tribulus teresteris 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 begining of the trial, 7th day and one month after end of the drug
Method of measurement
FSFI questionaire

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, 7days 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 questonnaire

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
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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

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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