Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

the effect of hydro alcohol extract of teribulus terisris on sexual function and satisfaction in post menopausal women

Protocol summary

Summary

The aim of this study was to determine the effect of consumption of hydro alcohol extract on desire, excitement, sexual satisfaction and orgasm in postmenopausal women. This is a double-blind clinical trial, which is referred to Ahvaz Health Center No. 1 in order to collect samples. samples of this study are among postmenopausal women. The sample size is 120 people who are randomly assigned to four groups of 30 people. Inclusion criteria: being married and gaining sexual function score less than 26.5 and exclusion criteria are body mass index of 30 or higher, and use of hormone therapy during the past 2 months .The samples will be asked to questionnaires of demographic information, sexual function and sexual satisfaction to complete. Drugs by third-party packaged and coded and randomly placed at the disposal of the samples. Tribulus terrestris extract syrup into three groups containing concentrations of 0.5 and 0.7 and 0.9 or to a placebo group is that each person should take two tablespoons daily for two months. After 4 weeks and again at the end of the second month questionnaires were distributed, and the total score evaluated and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121131340N1**
Registration date: **2017-07-23, 1396/05/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Mina Shojaee

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3161

Email address

shojaee.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-12-30, 1395/10/10

Expected recruitment end date

2017-03-30, 1396/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of hydro alcohol extract of teribulus terisris on sexual function and satisfaction in post menopausal women

Public title

Tribulus terrestris effect on satisfuction and sexual function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:Postmenopausal women; reading and writing skills Exclusion Criteria:BMI 30 or higher; use of hormone therapy

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

using Random number table method for this study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Ave, Ahvaz, Iran

City

Ahvaz

Postal code

6135715794

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.519

Health conditions studied

1

Description of health condition studied

sexual dys function

ICD-10 code

F52.0

ICD-10 code description

Either the prospect of sexual interaction produces sufficient fear or anxiety that sexual activity is avoided (sexual aversion) or sexual responses occur normally and orgasm is experienced but there is a lack of appropriate pleasure (lack of sexual enjoym

Primary outcomes

1

Description

Sexual Function

Timepoint

Before intervention,After 4 weeks and After 2 months

Method of measurement

FSFI Questionnaire

2

Description

Sexual Satisfaction

Timepoint

Before intervention,After 4 weeks and After 2 months

Method of measurement

Larenson Questionnaire

Secondary outcomes

1

Description

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Timepoint

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Method of measurement

_

Intervention groups

1

Description

Intervention group 3:The Extract of HydroAlcolol of Teribulus Teristris, Syrup in 0.9 mg/dl Twice per day in 2 months

Category

Treatment - Drugs

2

Description

Control group: syrups containing mannitol concentration of 0.5 Mg dl, twice a day for two months

Category

Treatment - Drugs

3

Description

Intervention group 1:The Extract of HydroAlcolol of Teribulus Teristris, Syrup in 0.5 mg/dl Twice per day in 2 months

Category

Treatment - Drugs

4

Description

Intervention group 2:The Extract of HydroAlcolol of Teribulus Teristris, Syrup in 0.7 mg/dl Twice per day in 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 1 city of Ahvaz

Full name of responsible person

Mina Shojaee

Street address

Sheikh Bahai South Ave, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences ,vice chancellor for research

Full name of responsible person

Mina Shojaee

Street address

Golestan Ave, Ahvaz, Khozestan

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences ,vice chancellor for research

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mina shojaee

Position

Midwifery student

Other areas of specialty/work

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Other areas of specialty/work

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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