

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Short -term effect of vaginal Hop (Humuluslupulus L.) on sexual function in women with menopausal symptoms

Protocol summary

2021-07-18, 1400/04/27

Study aim

Evaluation of the short-term effect of hops on sexual function in postmenopausal women referred to gynecological clinics affiliated to Kashan University of Medical Sciences in 2020-2021

Design

A clinical trial with the control group, with parallel groups, phase 3 on 60 patients.

Settings and conduct

This clinical trial on postmenopausal married women over 45 years of age who refer to Kashan University of Medical Sciences affiliated gynecological clinics due to menopausal problems

Participants/Inclusion and exclusion criteria

Inclusion criteria: All married women over the age of 45 who have had amenorrhea for at least a year and are experiencing menopause for the first time
Exclusion criteria: Patients who are allergic to hops or estradiol, estrogen-dependent cancers

Intervention groups

The groups were treated for two months with vaginal estradiol 0.625 mg for 21 nights and 7 nights rest and the other group was treated with hops vaginal extract.

Main outcome variables

Sexual desire, sexual arousal, vaginal lubrication, orgasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210405050859N1**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

Registrant information

Name

Samira Ferdosi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5550 0111

Email address

ferdosi-s@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short -term effect of vaginal Hop (Humuluslupulus L.) on sexual function in women with menopausal symptoms

Public title

The effect of hops on female sexual function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All married women over the age of 45 who have had amenorrhea for at least a year and are experiencing menopause for the first time

Exclusion criteria:

Patients who are allergic to hops or estradiol Estrogen-dependent cancers Concomitant use of drugs that interfere with sexual function Underlying diseases including diabetes Liver disorders, seizures, and autoimmune diseases Smoking and alcohol consumption

Age

From **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 in Biomedical Research

Street address

Medical School-Nurse Boulevard-Qotb Ravandi
Boulevard

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.206

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Sexual desire

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

brief questionnaire measure of sexual functioning in women

2

Description

Sexual arousal

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

brief questionnaire measure of sexual functioning in women

3

Description

Sexual slippage

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

brief questionnaire measure of sexual functioning in women

4

Description

Orgasem

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

brief questionnaire measure of sexual functioning in women

5

Description

Sexual satisfaction

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

brief questionnaire measure of sexual functioning in women

6

Description

Pain during intercourse

Timepoint

Before intervention and 4 weeks after starting the drug

Method of measurement

Brief questionnaire measure of sexual functioning in women

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vaginal estradiol 0.625 mg for 21 nights and 7 nights rest.

Category

Treatment - Drugs

2

Description

Intervention group: Razak vaginal extract (vaginal gel made in Iran and Barij Essential Oil Company of Kashan) is applied every night for a week and then twice a week for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Affiliated gynecological clinics of Kashan University of Medical Sciences

Full name of responsible person

Zahra Vahedpour

Street address

Kashan University of Medical Sciences-Qotb Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

zahravahedpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hossain Motedayen

Street address

Research Assistant-Kashan University of Medical Sciences-Qotb Ravandi Blvd-

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

hmotedayyen@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zahra Vahedpour

Position

Associated

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

School of Medicine- University of Medical Sciences-Qotb Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

zahravahedpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zahra Vahedpour

Position

Associated

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street addressSchool of Medicine- University of Medical Sciences-
Qotb Ravandi Blvd**City**

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

zahravahedpoor@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zahra Vahedpour

Position

Associated

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street addressSchool of Medicine- University of Medical Sciences-
Qotb Ravandi Blvd**City**

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

zahravahedpoor@gmail.com

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

Not applicable

Informed Consent FormUndecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/documentPart of the data such as information about the main
outcome or the like can be shared.**When the data will become available and for how long**

2 months after printing the results

To whom data/document is available

Researchers

Under which criteria data/document could be used

No analysis is allowed

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

Request via email

Comments