

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of increased clitoral blood flow on libido in women with decreased libido

Protocol summary

Study aim

The effect of increased clitoral blood flow via radio frequency wave on libido in women with decreased libido

Design

Forty-six married women with decreased libido who meet the inclusion criteria are randomly divided into intervention and control groups.

Settings and conduct

This study is performed in Farshchian Hospital in Hamadan. Intervention group: Up to three times every ten days, they use monopolar RF tools with both warm-up techniques and high-power endo gym in the vagina. In the control group, monopolar RF instruments are used up to three times every ten days using the low power endo gym technique without heating in the vagin

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married and have at least 6 months of continuous sexual relationship with a partner-No childbirth in the last 12 months- No breastfeeding in the last three months-Negative pregnancy test. Exclusion criteria: erectile dysfunction or other obvious sexual disorders in the patient's spouse - use of drugs that cause sexual disorders - concomitant medical illness - substance abuse

Intervention groups

Intervention group: Up to three times every ten days, they use monopolar RF tools with both warm-up techniques and high-power endo gym in the vagina. Control group: Up to three times every ten days of monopolar RF instrument using low power endo gym technique without heating in the vagina.

Main outcome variables

Marital Satisfaction - Depression and Women's Sexual Desire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N6**

Registration date: **2021-01-05, 1399/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-05, 1399/10/16**

Update count: **0**

Registration date

2021-01-05, 1399/10/16

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

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m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

1960-12-22, 1339/10/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of increased clitoral blood flow on libido in women with decreased libido

Public title

Effect of increased clitoral blood flow on libido

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Married and have at least 6 months of continuous sexual relationship with a partner No childbirth in the last 12 months No breastfeeding in the last three months Negative pregnancy test

Exclusion criteria:

Erectile dysfunction or other obvious sexual disorders in the patient's spouse Taking drugs that cause sexual disorders Simultaneous medical illness Substance abuse

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **56**

More than 1 sample in each individual

Number of samples in each individual: **23**

Number of samples in each individual: 23

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to the intervention and control groups using block randomization The patients will be randomly assigned to the intervention and control groups using block randomization Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number (between 1 and 6) to each of them 3)Choosing random numbers between 1 and 6 4) Defining the treatment assignment list

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the examining physician will not be aware of the patient's type of drug treatment, so the study will be performed in a double-blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

1960-12-20, 1339/09/29

Ethics committee reference number

IR.UMSHA.REC.1399.784

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

Lack or loss of sexual desire

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

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

female sexual desire

Timepoint

At the start of intervention- After intervention

Method of measurement

Using the Female Sexual Function Index questionnaire

2**Description**

Marital satisfaction

Timepoint

At the start of intervention- After intervention

Method of measurement

Using the Enriching and Nurturing Relationship Issues, Communication and Happiness(ENRICH) questionnaire

3**Description**

Depression rate

Timepoint

At the start of intervention- After intervention

Method of measurement

Hamilton Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Up to three times every ten days of monopolar RF instrument using low power endo gym technique without heating in the vagina.

Category

Treatment - Devices

2

Description

Intervention group: Up to three times every ten days, they use monopolar RF tools with both warm-up techniques and high-power endo gym in the vagina.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mohammad Haghighi

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honarestan Str.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available