

# 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

##### Email address

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

#### Street address

honarestan Str.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 1828 5015

#### Email

haghighi@umsha.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr Saeid Bashirian

#### Street address

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

#### City

Hamadan

#### Province

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#### Postal code

6517838695

#### Phone

+98 81 3838 0717

#### Email

haghighi@umsha.ac.ir

### 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

#### Street address

Farshchian Hospital

#### City

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#### Postal code

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#### Phone

+98 81182851015

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haghighi@umsha.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

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Mohammad Haghighi

#### Position

Professor of Psychiatry

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Specialist

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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