

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of Mariana on sexual function and sexual satisfaction of women in reproductive age

#### Protocol summary

##### Study aim

Determining the Effect of Mariana on Sexual Function and Sexual Satisfaction of Married Women of Reproductive Age Referred to Ardabil Health Centers in 2019

##### Design

This study is a clinical trial with randomized, double-blind, and control blocks.

##### Settings and conduct

The research community will include married women who visit health centers. People will receive the Gender Sexual Function Index (FSFI) questionnaire to determine their sexual function and people with a sexual function score below 28 (sexual dysfunction) will be included in the study as a unit of study and will receive a standard Larson sexual satisfaction questionnaire to determine their sexual satisfaction. The subjects were randomly divided into two groups of case and control. Gels will be provided to research units along with the FSFI questionnaire. Each research unit will be given a 30 gr tube. The vaginal unit will use vaginal gel for 4 weeks, 2 times a week and every half hour before an applicator approaches.

##### Participants/Inclusion and exclusion criteria

The research population included all married women referring to Ardabil health centers in 2019-2020 The criteria for entering units in this study will be: Age of 45-15 years Having a history of at least one year of having sex with her husband Voluntary consent to participate in the research Having a minimum level of education at the third level of middle school Exit criteria will be: Menopause Having any kind of physical illness and mental disorders in one individual and her husband The use of any psychoactive substance or psychoactive substance or sexual drugs during the intervention by the individual and her husband Pregnancy or having a pregnancy intention

##### Intervention groups

Mariana group. Placebo group

#### Main outcome variables

sexual function.sexual satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190425043369N1**

Registration date: **2019-11-30, 1398/09/09**

Registration timing: **prospective**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

##### Registration date

2019-11-30, 1398/09/09

##### Registrant information

##### Name

Elham Najafi Mollabashi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3372 1831

##### Email address

elhamnajafi94@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-23, 1398/10/02

##### Expected recruitment end date

2020-02-21, 1398/12/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of Mariana on sexual function and sexual satisfaction of women in reproductive age

**Public title**

The effect of Mariana on sexual function and sexual satisfaction of women in reproductive age

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 45-15 years Having a history of at least one year of having sex with her husband Voluntary consent to participate in the research Having a minimum level of education at the third level of middle school

**Exclusion criteria:**

Menopause Having any kind of physical illness and mental disorders in one individual and her husband The use of any psychoactive substance or psychoactive substance or sexual drugs during the intervention by the individual and her husband Pregnancy or having a pregnancy intention

**Age**

From **15 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples were randomly divided into two intervention and control groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

For this purpose, each of the two drugs will be prepared in identical shapes and will be provided by the pharmacist in packages with codes A and B and will be presented with the codes A and B.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

National Committee on Biomedical Research of Ardabil University of Medical Sciences

**Street address**

Ferdowsi Street. Ferdows Alley

**City**

Ardabile

**Province**

Ardabil

**Postal code**

5615675494

**Approval date**

2019-11-11, 1398/08/20

**Ethics committee reference number**

IR.ARUMS>REC.1398.440

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

Sexual function

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

sexual satisfaction

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sexual performance

**Timepoint**

At the beginning of the study and after a month of using the gel

**Method of measurement**

Female Sexual Function Index, FSFI

**2****Description**

sexual satisfaction

**Timepoint**

At the beginning of the study and after a month of using the gel

**Method of measurement**

Larson Sexual Satisfaction Questionnaire

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: Mariana group

### Category

Treatment - Drugs

2

### Description

Control group: Placebo group

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Health Centers

#### Full name of responsible person

Hatam

#### Street address

Saadi ST

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5615675494

#### Phone

+98 45 3372 1831

#### Email

elhamnajafi94@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ardabil University of Medical Sciences

#### Full name of responsible person

Moolaei

#### Street address

Saaedi ST

#### City

Ardabil

#### Province

Ardabil

#### Postal code

561567896

#### Phone

+98 45 3371 3272

#### Email

gamisi11@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

#### Full name of responsible person

Elham Najafi Mollabashi

#### Position

coach

#### Latest degree

Master

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

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#### City

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#### Province

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#### Postal code

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ardabil University of Medical Sciences

#### Full name of responsible person

Elham Najafi Mollabashi

#### Position

Coach

#### Latest degree

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#### Other areas of specialty/work

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**Phone**

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**Email**

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

Ardabil University of Medical Sciences

**Full name of responsible person**

Elham Najafi Mollabashi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Gynecology and Obstetrics

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**City**

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elhamnajafi94@yahoo.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**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Main outcome information

**When the data will become available and for how long**

Start the access period 12 months after printing the results

**To whom data/document is available**

researchers

**Under which criteria data/document could be used**

No more information

**From where data/document is obtainable**

Elham Najafi Mollabashi email:  
elhamnajafi94@yahoo.com

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

send mail

**Comments**