Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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+98 45 3372 1831
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Moolaei
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561567896
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+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
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Person responsible for updating data

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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