Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of Lactofem supplementation on sexual performance of women with depression compared to antidepressant treatment alone

Protocol summary

Study aim
Evaluating the effect of Lactofem supplementation on sexual performance of women with depression compared to antidepressant treatment alone

Design
The clinical trial has a control group, with parallel groups, randomized, phase 3 on 104 patients with depression treated with antidepressants. The random assignment sequence will be determined using the computer program "Computer Random Generation".

Settings and conduct
This research will be conducted on 104 patients with depression treated with anti-depressants in Shahid Muftah Clinic, Yasuj . Patients will be divided into two intervention groups (receive lactofem supplement in addition to antidepressants) and control (take antidepressants alone).

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18-45 years; Reading and writing literacy; scoring less than 20 and diagnosing mild to moderate depression on the Hamilton scale; being treated for at least 4 weeks with antidepressants that affect sexual performance; Marital status; having sex at least once a month; having an emotionally satisfying relationship with a stable and sexually active spouse for at least one year. Exclusion criteria: suffering from women's diseases and vaginitis and sexual disorders with an organic background according to the statement of the research unit; sexual problems before taking antidepressants; symptoms of psychosis; loss of relatives, acquaintances or friends during the last six months; known sexual problem in men; current pregnancy and breastfeeding.

Intervention groups
Intervention group: Antidepressant drug plus one Lactofem capsule was administered daily for three months. Control group: Antidepressant drug alone.

Main outcome variables
Sexual function, Depression severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160524028038N14**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-19, 1401/09/28**
Update count: **0**

Registration date
2022-12-19, 1401/09/28

Registrant information

Name
Fatemeh Bazarganipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3366 6367

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-11, 1401/09/20

Expected recruitment end date
2023-03-19, 1401/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Lactofem supplementation on sexual performance of women with depression compared to antidepressant treatment alone

Public title

Lactofem and sexual function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 years Reading and writing literacy Obtaining a score of less than twenty and diagnosing mild to moderate depression on the Hamilton scale For at least 4 weeks, be treated with anti-depressants that affect sexual function Marriage Having sex at least once a month Having an emotionally satisfying relationship with a stable and sexually active spouse for at least one year Desire to participation

Exclusion criteria:

The unwillingness of the research unit during sampling, which will lead to his withdrawal from the study Having speech or hearing problems Addiction to drugs and alcohol in a person or his spouse Getting women's diseases and vaginitis and sexual disorders with organic background according to the statement of the research unit Sexual problem before taking antidepressants symptoms of psychosis Loss of relatives, acquaintances or friends during the last six months Known sexual problem in men Current pregnancy and breastfeeding Suffering from internal diseases such as cardiovascular, thyroid, arthritis, diabetes, epilepsy, kidney infection Taking birth control pills Taking drugs that affect sexual performance, such as blood pressure reducers, antihistamine H2 blockers, barbiturates).

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple; Random unit: Individual; Randomization tool: Statistical software “computer; Hiding method: Use 104 sealed envelopes encoded and non-transparent in the package for the allocation of subjects to intervention and control groups. The research units will be divided into two clinical groups with a ratio of 1:1 using the software to receive antidepressants alone or Lactofem supplement.

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 of Yasuj University of Medical Sciences

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad

City

kohgiluyeh and boyer-ahmad

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.YUMS.REC.1401.078

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Female sexual function index

2

Description

Depression severity

Timepoint

Before the intervention and three months after the

intervention

Method of measurement

Beck depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Selective serotonin reuptake inhibitor (SSRI) antidepressants plus one Lactofem capsule (including Lactobacillus acidophilus 109 ، 2, Bifidobacterium bifidus 109 ، 2, Lactobacillus rutri 2 × 109, Lactobacillus fermentum 109 × 2; capsule weight of 500 mg bio-capsule) made by Iranian zist-takhmir Company was administered daily for 3 months orally.

Category

Treatment - Drugs

2

Description

Control group: Taking selective serotonin reuptake inhibitor (SSRI) antidepressants such as fluoxetine, sertraline, fluvoxamine, citalopram, escitalopram, paroxetine alone.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasuj University of medical sciences, Shahid Mofateh Clinic

Full name of responsible person

Raana Moshtaghi

Street address

Yasuj University of medical sciences, Shahid Mofateh Clinic, Motahari Bulvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Amin Hosseini

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Raana Moshtaghi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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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
No more information
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