Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison between Diltiazem gel 2% and lubricating gel effects on female with sexual dysfunction refer to psychosexual clinic

Protocol summary

Study aim
Evaluation and comparison between diltiazem gel 2% and lubricant gel in improving sexual function in women with sexual dysfunction

Design
Parallel clinical trial

Settings and conduct
Intervention groups include women referred to the psychosocial clinic of Taleghani Hospital who have sexual dysfunction and difficulty having sex with their partner. One group is given a lubricant gel and the other group is given diltiazem gel 2%, and at the beginning of the study and at the end of the fifth week, the change in women's satisfaction is measured with the FSFI criteria.

Participants/Inclusion and exclusion criteria
Patients' satisfaction to participate in the study؛ having sex for at least one year؛ sexual dysfunction and dissatisfaction with sex for at least 6 months

Intervention groups
This study is done in two groups. Patients are non-randomly divided into two groups and one group is given diltiazem gel 2% and the other group is given lubricant gel. This study will be done during 5 weeks, which FSFI will be evaluated at the beginning of the study and at the end of the fifth week.

Main outcome variables
Improve quality of life, increase sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100127003210N21**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **prospective**

Last update: **2021-04-04, 1400/01/15**
Update count: **0**

Registration date
2021-04-04, 1400/01/15

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-13, 1400/01/24

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison between Diltiazem gel 2% and lubricating gel effects on female with sexual dysfunction refer to psychosexual clinic

Public title
Evaluation and comparison between Diltiazem gel 2% and lubricating gel effects on female with sexual dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having sex with a partner for at least one year Having sexual dysfunction (FSD) for at least 6 months Patients' Satisfaction to participate in this study

Exclusion criteria:

Unwillingness of patients to continue to participate in the study History of allergic reactions to the drug Not taking the drug to treat vaginal atrophy in menopausal women No pregnancy and lactation Not recommended in patients with a history of low blood pressure, heart attack and pulmonary embolism

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Individual Randomization with the Card in Two Groups A and B, in this Way a Number of Cards are selected as the first Intervention Group and the same Number in the second Intervention Group, then by merging the Cards together one Card is drawn and its Allocation is recorded and the Card is returned to the other Cards after it has been removed. The Cards are then re-merged and another Card is withdrawn. The Process continues until a Random Sequence Sample Size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti School of Pharmacy, Hashemi Rafsanjani Highway ,Valiasr St.

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1996835113

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.317

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

Improving sexual performance and satisfaction in women by measuring the increase of FSFI score

Timepoint

At the beginning of the study, the first week, the second week, the third week, the fourth week, the fifth week

Method of measurement

FSFI

Secondary outcomes

1

Description

Improving the quality and satisfaction of sexual intercourse in women

Timepoint

The beginning of the study and the end of the study

Method of measurement

Female Sexual Function Index (FSFI) questionnaire

Intervention groups

1

Description

Intervention group:In people with a history of sexual dysfunction, the effect of diltiazem topical gel 2% on improving sexual function is investigated.Thus, before starting the study and also after using diltiazem gel 2% for 5 times in a period of 5 weeks, the FSFI questionnaire should be filled in by the person participating in the study and the score changes in this intervention are measured.This gel is used externally in the outer part of the vagina. Also, for better effect, it should be used one hour before intercourse.

Category

Other

2

Description
Control group: In this study, lubricant gel is used to compare the effect of diltiazem gel 2% with placebo. The duration of the study period in this group is 5 weeks and the number of uses is 5 times. Before and at the end of the study, the FSFI questionnaire should be completed by individuals.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Helma Khademi Estahbanati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Helma Khademi Estahbanati

Position
Student of Pharmacy

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available