

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparing the Efficacy of Bupropion and Ritaline on women Sexual Dysfunction Induced by sertraline)

Protocol summary

Study aim

Comparison of two bupropion releasing agents and ritalin in reducing sexual dysfunction in women aged 20-45 years Candidate treatment with sertraline

Design

This is a one-way blind clinical trial. Two randomized groups of 25 patients are prescribed separately for each group. In each visit, the Arizona questionnaire is filled up by the researcher for the patient

Settings and conduct

Clinic of Yahyanejad and Rouhani hospitals who are candidates for psychiatric diagnosis receive one of the SSRIs (Sertraline) and according to the Arizona questionnaire there is no sexual dysfunction for them.

Participants/Inclusion and exclusion criteria

Women aged 20 to 45 years, according to psychiatric diagnosis, are candidates for one of the SSRIs (sertraline), and according to the Arizona questionnaire, they have no sexual dysfunction. The men were excluded from these exclusion criteria: history of any previous sexual dysfunction over the last 6 months Major depression, drug users and cigarettes or herbal medicines for the treatment of sexual dysfunction, the development of chronic illnesses that are being treated, such as diabetes, Liver or kidney disease, cardiovascular disease (through interviews), and those who do not adhere to the protocol were excluded.

Intervention groups

25 female patients aged 20 to 45 years undergoing bupropion medication with sertraline treated with sexual dysfunction
25 female patients aged 20 to 45 years undergoing ritaline medication with sertraline treated with sexual dysfunction

Main outcome variables

Sexual dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170606034348N2**
Registration date: **2018-09-19, 1397/06/28**
Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 121 3171

Email address

a.hamidia@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of Bupropion and Ritaline on women Sexual Dysfunction Induced by sertraline)

Public title
the Efficacy of Bupropion and Ritaline

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Female patient aged 20 to 45 years undergoing treatment with sertraline
Exclusion criteria:
History of any previous sexual dysfunction Consumers of any drugs and cigarettes or herbal medicines Previous chronic diseases

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were selected by convenience sampling method. 50 eligible participants were randomly divided into two groups of Bupropion treatment and Ritaline treatment. A randomized trial was conducted using binary random blocks. More precisely, accidental collisions were arranged Patients were enrolled in a pre-designed list that was randomly prescribed for one patient (Bupropion or Ritalin), so that the prescriber was not informed about the prescription drug (unilateral blindness).

Blinding (investigator's opinion)
Single blinded

Blinding description
The researcher will fill out the questionnaire on each visit, without any kind of medication

Placebo
Not used

Assignment
Parallel

Other design features
.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Babol University Of Medical Science
Street address

Yahya Nejad Hospital Ave
City
Babol
Province
Mazandaran
Postal code
4713566547

Approval date
2018-01-20, 1396/10/30
Ethics committee reference number
MUBABOL.HRI.REC.1396.165

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Score of sexual dysfunction in Arizona Sexual Experiences Scale questionnaire

Timepoint
.End of one month after treatment begins

Method of measurement
Arizona Sexual Experiences Scale is a short 5-point scale that evaluates sexual performance, especially sexuality, arousal, orgasm's ability to achieve orgasm during the next week. Arizona Sexual Experiences Scale, a tool for assessing sexual misconduct due to side effects of drug interventions in patients with depression or anxiety disorder, is filled by a person in charge of the research.

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group 1": In female patients aged 20 to 45 years with sertraline treatment that has been associated with sexual dysfunction during treatment with this drug, Ritalin tablet (methylphenidate) from Novartis Pharmaceutical company at a dose of 5 mg one hour before sex (PRN) It is prescribed for one month.

Category
Placebo

2

Description

"Intervention group 2": Female patients aged 20 to 45 years with sertraline treatment who have had a sexual dysfunction during the treatment; the Bupropion (wellban) tablet from the Abidi Pharmaceutical Company at a dose of 150 mg daily (evening) for one month is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad Hospital And Rohani Hospital

Full name of responsible person

Haghpanah Fahimeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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?

No

Title of funding source

Vice Chancellor for research and technology, Babol

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

Babol University of Medical Sciences

Full name of responsible person

Angela Hamidia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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