

# 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

##### Street address

Emam khomeini Ave

##### City

Babol

##### Province

Mazandaran

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4713566547

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+98 11 3229 1951

##### Email

fahimeh.haghpanah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Angela Hamidia

##### Street address

Blv Keshavarz

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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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##### Position

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##### Latest degree

Specialist

##### Other areas of specialty/work

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**Person responsible for updating data**

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**Other areas of specialty/work**

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**Email**

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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