Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of efficacy and safety of aripiprazole in treatment of Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) induced sexual dysfunction: a randomized double blind controlled trial

Protocol summary

Summary

The aim of this study is to evaluate efficacy and safety of aripiprazole as adjunctive therapy in treatment of sexual dysfunction due to Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs). Sixty eligible outpatients are randomly divided into the intervention and control groups. Subjects in the intervention group receive aripiprazole with an initial dose of 5 milligram aripiprazole per day on the first week, then 10 milligrams per day on the second week and finally the dose will increase to 15 milligrams per day on the third week and continue with the same dose along with SSRIs or SNRIs for six weeks. The placebo group receive placebo tablets, which made as same as aripiprazole, along with their usual regimen for six weeks. The dose of SSRIs or SNRIs will be remained constant during the study period and only co- medication with benzodiazepines is allowed. Arizona Sexual Experience Involuntary (ASEX), Female Sexual Function Index (FSFI), and International Index of Erectile Function (IIEF) are assessed at the baseline and on the 2, 4 and sixth weeks. Side effects will be assessed with Barns Akathisia Rating Scale (BARS) and Abnormal Involuntary Movement Scale (AIMS) at the baseline and on the 2, 4 and sixth weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020432236N5**
Registration date: **2017-04-02, 1396/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Narjes Hendouei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of aripiprazole in treatment of Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) induced sexual dysfunction: a randomized double

blind controlled trial

Public title
Effect of aripiprazole in treatment of sexual dysfunction due to antidepressants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Outpatients with psychiatric disorders according to the fifth edition of Diagnostic and Statistical Manual of Psychiatric Disorders treated with serotonin specific reuptake inhibitor or serotonin norepinephrine reuptake inhibitor in the age range of 18-50 year-old; Suffer from sexual dysfunction according to the fifth edition of Diagnostic and Statistical Manual of Psychiatric Disorders; Having a regular and satisfying sexual activity before taking the serotonin specific reuptake inhibitor or serotonin norepinephrine reuptake inhibitor; Enable in sexual function Exclusion criteria: Having sexual dysfunction before serotonin specific reuptake inhibitor or serotonin norepinephrine reuptake inhibitor; History of substance use interfere with sexual function (eg, alcohol, drugs, drug abuse or dependence during the past twelve months or positive urine test for illicit drugs); Electroconvulsive therapy during the 6 past months; Suicidality(active suicide or homicide intent, or a suicide or homicide attempt in the preceding 6 months); Mental retardation; Pregnant or at risk of pregnancy; Cognitive disorders such as dementia, delirium, or amnesia, traumatic brain injury; Current significant unstable medical illness (such as unstable cardiac disease, hepatic or renal impairment, evidence or history of malignancy or any significant hematological, endocrine); Axis II psychiatric disorders; Family history of bipolar disorder; Concomitant use with other psychiatric drugs; Hypersensitivity to aripiprazole; Previous treatment with aripiprazole in the past year; History of neuroleptic malignant syndrome; Unwilling or unable, in the opinion of the Investigator, to comply with study instructions
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
This is a randomized double blind controlled study. The participants and assessor are aware of neither drugs nor placebo. The block randomization method is used .

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice president of research, Mazandaran University of Medical Sciences
Street address
Vice president of research, Mazandaran University of Medical Sciences, Moallem street, Moallem square, Sari, Mazandaran, Iran
City
Sari
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.MAZUMS.REC.95-1976

Health conditions studied

1

Description of health condition studied
Sexual desire
ICD-10 code
F52.0
ICD-10 code description
Lack or loss of sexual desire

2

Description of health condition studied
Sexual dysfunction
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

3

Description of health condition studied
Orgasm
ICD-10 code
F52.3
ICD-10 code description
Orgasmic dysfunction

4

Description of health condition studied
Ejaculation
ICD-10 code
F52.4
ICD-10 code description

Premature ejaculation

Primary outcomes

1

Description
Sexual function enhancement
Timepoint
weeks 0,2,4,6
Method of measurement
Arizona Sexual Experience Involuntary (ASEX), Female Sexual Function Index (FSFI), International Index of Erectile Function (IIEF)

Secondary outcomes

1

Description
Akathisia advers effect due to aripiprazole
Timepoint
weeks0,2,4,6
Method of measurement
Barns Akathisia Rating Scale (BARS)

2

Description
Movement effect of aripiprazole
Timepoint
weeks0,2,4,6
Method of measurement
Abnormal Involuntary Movement Scale (AIMS)

Intervention groups

1

Description
Subjects in the intervention group receive aripiprazole with an initial dose of 5 milligram aripiprazole per day on the first week, then 10 milligrams per day on the second week and finally the dose will increase to 15 milligrams per day on the third week and continue with the same dose along with SSRIs or SNRIs for six weeks
Category
Treatment - Drugs

2

Description
The placebo group receive placebo, which made as same as aripiprazole, along with their SSRIs or SNRIs regimen for six weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric clinic of Noor hospital in Isfahan
Full name of responsible person
Dr Gholam Hossein Ahmadzadeh
Street address
Noor (Khorshid) hospital, Ostandari street, Isfahan, Iran
City
Isfahan

2

Recruitment center
Name of recruitment center
Psychiatric clinic of Moddarres hospital in Isfahan
Full name of responsible person
Dr Mehrdad Salehi
Street address
Moddarres hospital, Goldasht street, Najaf abad road, Isfahan, Iran
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmad Ali Enayati
Street address
Mazandaran University of Medical Sciences, Moallem street, Moallem square, Sari, Mazandaran, Iran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity

Mazandaran University of Medical Sciences
Full name of responsible person
Dr Narjes Hendouei
Position
Assistant professor
Other areas of specialty/work
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Postal code
Phone
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty