

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of Bupropion Efficacy on Sexual Dysfunction among Male Patients on Methadone Maintenance Therapy

Protocol summary

Summary

The study was designed to investigate the efficacy of bupropion on sexual dysfunction in men receiving Methadone maintenance therapy (MMT) in addiction quitting center of Noor anad St.Aliasghar Hospital of Isfahan. During a double-blinded, placebo-controlled trial 60 male patients receiving Methadone maintenance therapy randomized to treatment(n=30) with bupropione (200 mg/day) or placebo(n=30) for 8 weeks.Male patients who received Methadone- maintained Therapy for at least 6 months, having complaints of sexual dysfunction after receiving methadone treatment, were entered the study Other inclusion criteria were: A negative history of underlying diseases such as epilepsy, diabetes, organic brain disease, and psychosis, and not receiving drugs affecting sexual function, no risk of major depressive disorder and a score of less than 16 based on the BDI-II, having a total score of 19 or more based on the Arizona Sexual Experience Scale (ASEX), no alcohol consumption . The exclusion criteria were consisted of leaving the MMT program, the decision of the therapist to stop the treatment with methadone or bupropion for any reason, and seizures. Sexual function and depression score were assessed by Arizona sexual experience scale (AXES), and Beck depression inventory II (BDI-II) self-reported questionnaires, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014032616823N1**

Registration date: **2014-03-26, 1393/01/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-26, 1393/01/06

Registrant information

Name

Mehrdad Salehi

Name of organization / entity

Isfahan University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences-Behavioral Sciences Research Center

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Bupropion Efficacy on Sexual Dysfunction among Male Patients on Methadone Maintenance Therapy

Public title

Evaluation of Bupropion Efficacy on Sexual Dysfunction among Male Patients on Methadone Maintenance Therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male gender; Having the minimum level of education in reading and writing; passing at least 6 months from the Methadone maintenance Therapy (MMT); Having complaints from the cause or aggravate of sexual dysfunction after methadone treatment; Lack of underlying diseases as epilepsy, diabetes, organic brain disease, and psychosis; Not receiving drugs affecting sexual function, such as SSRI, sildenafil, testosterone, antipsychotics, cyclic antidepressants, MAO-I, the lithium, amphetamines, clordiazepoxide, clonidine, methyl dopa, spironolactone hydrochlorothiazide, barbiturates, anti-Parkinson's drugs, clofibrate, digoxin, indomethacin, propranolol and phentolamine; No risk of major depressive disorder and a score of less than 16 based on the BDI-II, Having a total score of 19 or more based on the Arizona Sexual Experience Scale (ASEX) or a score of 5 or more on one of the items of ASEX or a score of 4 or more in any of 3 items; No alcohol consumption, recent cessation of benzodiazepines, and not using drugs or stimulants. Exclusion criteria: Leaving the MMT program; the decision of the therapist to stop the treatment with methadone or bupropion for any reason, and seizures.

Age

No age limit

Gender

Male

Phase

N/A

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib street

City

Isfahan

Postal code

Approval date

2009-06-09, 1388/03/19

Ethics committee reference number

388223

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52.0

ICD-10 code description

Lack or loss of sexual desire

Primary outcomes

1

Description

sexual function

Timepoint

preintervention, post intervention at the end of 2, 4, 6, and 8 weeks

Method of measurement

Arizona sexual experiences scale (ASEX)

Secondary outcomes

1

Description

Depression total score

Timepoint

preintervention, post intervention at the end of 2, 4, 6 and 8 weeks

Method of measurement

Beck depression scale

Intervention groups

1

Description

intervention group- bupropion tab.100 mg Po for 3 days, then twice daily (200mg/day) for 8 weeks.

Category

Treatment - Drugs

2

Description

control group: Placebo tab.100 mg po for 3 days, then twice daily (200mg/day) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction Quitting clinic- Noor & st.Aliaghar hospital

Full name of responsible person

Dr.Mehrdad Salehi

Street address

Ostandari street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences-Behavioral Sciences Research Center

Full name of responsible person

Dr.Mehrdad Salehi

Street address

Ostandari street- Noor & St.Aliasghar hospital Hospital

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences-Behavioral Sciences Research Center

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

Behavioral Sciences Research Center- Isfahan University of Medical Sciences

Full name of responsible person

Mehrdad Salehi

Position

Associate professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Behavioral Sciences Reserach Center-Isfahan University of Medical Sciences

Full name of responsible person

Mehrdad Salehi

Position

Psychiatry specialist(MD)

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University Isfahan (khorasgan Branch)

Full name of responsible person

Mitra Molaeinezhad

Position

PhD/ Faculty member

Other areas of specialty/work

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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