

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2014-03-26, 1393/01/06

#### 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.

#### Registrant information

##### Name

Mehrdad Salehi

##### Name of organization / entity

Isfahan University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1234 5711

##### Email address

me\_salehi@med.mui.ac.ir

#### 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

#### 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

## 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**

**Street address**

ostandari street- Noor & st. Aliasghar Hospital

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1222 2475

**Fax**

**Email**

me\_salehi@med.mui.ac.ir

**Web page address**

## 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)

**Other areas of specialty/work**

**Street address**

Ostandari street- Noor & st.Aliasghar Hospital

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1222 2475

**Fax**

**Email**

me\_salehi@med.mui.ac.ir

**Web page address**

## 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**

**Street address**

Islamic Azad University Isfahan( khorasgan branch)

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1535 4065

**Fax**

**Email**

melika1353@yahoo.com

**Web page address**

http://drmolaei.ir

## 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*