

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Therapeutic Effect of Varenicline on Depression among Smokers Methadone Maintenance Therapy

Protocol summary

Study aim

Evaluation of therapeutic effect of varenicline on depression among methadone maintained smokers with major depressive disorder

Design

Double Blind randomized clinical trial with parallel group design

Settings and conduct

Sixty (60) smokers who referred to Yazd addiction treatment clinics and had a primary diagnosis of depression based on the DSM 5 criteria, were randomly divided into two groups of varenicline and placebo

Participants/Inclusion and exclusion criteria

Inclusion criteria: Persons in ranged 18 to 60 years old ; Smokers under methadone maintenance therapy; Patients with major depressive disorder; Non inclusion criteria: Create a noticeable and persistent drug problem; Have a systemic disease ; Patients with substance use (Based on Self-report); Patients with psychotic disorder; Patients with suicidal thoughts; The patients under treatment with psychiatric drugs; Depression is follow to substance use ; Depression is associated with medical illness; The patient is taking drugs that cause depression.

Intervention groups

Intervention group: The varenicline group, receiving the first three days , 0.5 mg and then 1 mg of varicellin (manufactured by Kowsar Pharmacy Company), received as daily for 6 weeks. Control group: Placebo group. The starch was prepared in capsule form and was taken for 6 weeks. In both groups, citalopram 20 mg/day were be given for 6 weeks.

Main outcome variables

Depression Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190308042972N1**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

mohammad talebpoorardakani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3222 1357

Email address

m_talebpoor@yahoo.com.au

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-11-11, 1397/08/20

Trial completion date

2018-12-06, 1397/09/15

Scientific title

Evaluation of Therapeutic Effect of Varenicline on Depression among Smokers Methadone Maintenance Therapy

Public title

The effect of varenicline on depression in smokers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Persons in ranged 18 to 60 years old Smokers under methadone maintenance therapy Patients with Major depressive disorder

Exclusion criteria:

The patient's desire to withdraw from the study Create a noticeable and persistent drug problem Have a systemic disease Patients with substance use (Based on Self-report) Patients with psychotic disorder Patients with suicidal thoughts The patients under treatment with psychiatric drugs Depression is follow to substance use Depression is associated with medical illness The patient is taking drugs that cause depression

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

By using simple randomized method, individuals were randomly assigned to control and intervention groups. The direction to read random numbers was from the left side. Even numbers were considered for the intervention group and the odd numbers for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug was prepared by a pharmacist that did Varenicline and placebo (starch) in the form of similar capsules and divided into two groups A and B. Until the end of the study, the participants, patients under methadone treatment, residence , and statistics counselor were not informed .

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Headquarters of the University of Medical Sciences, Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8951643745

Approval date

2017-09-03, 1396/06/12

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.179

Health conditions studied**1****Description of health condition studied**

major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes**1****Description**

Depression Score

Timepoint

First, 3 weeks later, 6 weeks later

Method of measurement

Beck Depression Inventory(I-II)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Citalopram tablet was given 20 mg once a day for 6 weeks and Vareniclin tablet (produced by Kowsar Pharmacy Company) 0.5 mg daily for the first three days and then 1 mg tablet daily for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Citalopram tablets 20 mg per day and placebo (starch) in the form of capsules was given one day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Dastjerdi's addiction treatment clinic

Full name of responsible person

Dr. Ghasem Dastjerdi

Street address

Dr Dastjerdi Drug Treatment Clinic Shahid Hedayati Alley near Sina Lab, Taleghani Blvd, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

Headquarters of the Yazd University of Medical Sciences, Bahonar Square, Yazd

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Ghasem Dastjerdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Talebpoorardakani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available