

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of efficacy and safety of Haloperidol on symptoms of acute opioids withdrawal

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

The purpose of this randomized triple blind placebo controlled study is to compare the effectiveness and safety of haloperidol vs placebo in the management of acute opioid withdrawal symptoms. Inclusion criteria are DSM-5 criteria for opioid use disorder and exclusion criteria are sensitivity to haloperidol; poly substance use; major psychiatric disorders; severe medical illnesses; pregnancy and Lactation and mental retardation. Study population is patient with opioid drugs dependence, and sample size is 74. According to the Addiction Severity Index (ASI), patients will be divided to mild, moderate and severe dependence, and each of these groups will be randomly divided into placebo and haloperidol subgroups. For patients a fixed dose of methadone will be administered for 5 days according to the equivalent dosage of their previous opioid usage. Thereafter, over a period of 5 days, methadone will be reduced gradually (20% daily) until discontinued. Haloperidol/placebo and methadone will be started simultaneously. Haloperidol/placebo dosage is equivalent with the dosage of methadone; (patients receiving <15 mg, 15-30 mg, 30-45 and >45 mg methadone, will be administered 5, 10, 15 and 20mg, haloperidol/placebo daily respectively.) Haloperidol and placebo will be continued for one week after discontinuation of methadone and thereafter they will be reduced half a 5 mg tablet daily until discontinued. Duration of the study will be 19 to 25 days according to the type and dosage of opium usage. The Objective Opioid Withdrawal Scale (OOWS) will be used for assessment of withdrawal symptoms every other day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702131457N12**

Registration date: **2017-06-14, 1396/03/24**

Last update:

Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

Name

Mehran Zarghami

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences and Department of Psychiatry, Mazandaran Univ

Country

Iran (Islamic Republic of)

Phone

+98 15 1328 5659

Email address

mzarghami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences & Health Services

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of Haloperidol on symptoms of acute opioids withdrawal

Public title

Efficacy of haloperidol on symptom of opium withdrawal.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:A reliable history of opioids consumptions until the onset of the study; DSM-5 criteria for opioid use disorder; Positive urine rapid test of opioids Exclusion criteria:Enzyme inducers medication usage or other medical treatments;History of Sensitivity to haloperidol; Poly substance use (Cannabinoids ,Alcohol , barbiturates , benzodiazepines, analgesics) and use of antidepressants , other antipsychotics , beta blockers , alpha 2 agonists, inhibitors of CYP 3A4 , and CYP2D6 in the last month before study (except nicotine); Major depressive disorder, Bipolar mood disorder, severe anxiety disorders and Psychosis; Severe medical illnesses such as epilepsy, hepatitis, tuberculosis, AIDS, liver dysfunction, renal dysfunction; Pregnancy and Lactation; Electroconvulsive therapy in the last 6 months; Suicidal ideation or suicidal attempt at the beginning of the study or within the last 6 months; Mental retardation; Neurological disorder such as dementia, uncontrolled epilepsy and history of head trauma ; Past history of neuroleptic malignant syndrome.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mazandaran University of Medical Sciences & Health Services

Street address

NO.2 Building Mazandaran of Medical Sciences,Moallem Square

City

Sari

Postal code

4817844718

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.MAZUMS.REC.95.2298

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

Opium use disorder

ICD-10 code

F11.2

ICD-10 code description

Mental and behavioral disorders due to use of opioids_dependence syndrome

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

acute opioid withdrawal symptoms

Timepoint

every other day

Method of measurement

Objective opioid withdrawal scale

Secondary outcomes**1****Description**

extrapyramidal symptoms, serum prolactin level

Timepoint

Extrapyramidal symptoms will be assessed by everyday clinical assessment, prolactine; and serum prolactin level, before & after the end of the study

Method of measurement

History & Physical Exam & laboratory test

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

patients receiving 15 mg or less than 15 mg of methadone, 5 mg haloperidol will be administered each day; patients receiving 15 to 30 mg of methadone, haloperidol will be administered 10 mg daily; patients receiving 30 to 45 mg of methadone, will be administered 15 mg haloperidol daily; and patients receiving more than 45 mg methadone, will be administered 20 mg haloperidol daily. Haloperidol will be continued for one week after discontinuation of methadone and thereafter it will be reduced half a 5 mg tablet daily until discontinued.

Category
Placebo

2

Description

patients receiving 15 mg or less than 15 mg of methadone, 5 mg placebo will be administered each day; patients receiving 15 to 30 mg of methadone, placebo will be administered 10 mg daily; patients receiving 30 to 45 mg of methadone, will be administered 15 mg placebo daily; and patients receiving more than 45 mg methadone, will be administered 20 mg placebo daily. Placebo will be continued for one week after discontinuation of methadone and thereafter it will be reduced half a 5 mg tablet daily until discontinued

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Zare Psychiatric Hospital
Full name of responsible person
Mehran Zarghami
Street address
Neka Road, Zare Hospital
City
Sari

2

Recruitment center

Name of recruitment center
Zare Psychiatric Hospital
Full name of responsible person
Mehran Zarghami
Street address
Neka Road, Zare Hospital
City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmadali Enayati
Street address
Building No 2. Mazandaran University of Medical Sciences
City
Sari

Grant name

Grant code / Reference number
2298

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 Mehran Zarghami
Position
Professor
Other areas of specialty/work
Street address
NeKa Road Sari, Zare Hospital
City
Sari
Postal code
4815466848
Phone
+98 11 3328 5109
Fax
+98 11 3328 5109
Email
mehran.zarghami@gmail.com;
mzarghami@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Mehran Zarghami
Position
Professor
Other areas of specialty/work
Street address
Neka Road Sari,Zare Hospital
City
Sari
Postal code
4815466848
Phone
+98 11 3328 5109
Fax

+98 11 3328 5109

Email

mehran.zarghami@gmail.com;

mzarghami@mazums.ac.ir

Web page address

+98 11 3320 5397

Fax

+98 11 3328 5109

Email

fattaneh_ghaderi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of medical Sciences

Full name of responsible person

Fattaneh Ghaderi Bafti

Position

Psychiatry assistant

Other areas of specialty/work

Street address

No:1-Jam Building_salman farsi St.

City

Sari

Postal code

4818913731

Phone

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