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

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**

Registration timing: **registered_while_recruiting**

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

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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 & labratory 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
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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
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Dr Mehran Zarghami
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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