# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**

Iran (Islamic Republic of)

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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
**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## 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*