# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of buprenorphine and methadone maintenance treatments in prison: a randomized controlled trial

## Protocol summary

**Study aim**
Comparison of safety and efficacy of buprenorphine maintenance treatment with methadone maintenance treatment in prison

**Design**
Double blind, parallel group, phase 3 randomized controlled trial

**Settings and conduct**
Patients in the addiction ward of Ghezal Hesar prison were randomly assigned to the intervention group (buprenorphine) and active control (methadone) based on the designed protocol, and the treatment results were compared over 24 weeks period.

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria: 1- Diagnosis of moderate to severe opioid use disorder (opium, opium residue and heroin) based on DSM 5, 2- Continuous consumption of illegal opioids in the last period of consumption, 3- Age 18 to 50 years, 4- Conviction period more than 6 months, 5- To provide informed written consent. Exclusion criteria: 1- Concurrent diagnosis of other substance use disorders (except tobacco), 2- Uncontrolled severe psychiatric disorder, including serious suicidality and psychosis based on physician's diagnosis, 3- Severe and uncontrolled physical diseases including unstable angina, high blood pressure, liver failure, and recent (last month) history of myocardial infarction based on a physician' s diagnosis and laboratory tests, 4- Pregnancy and lactation, 5- Inability to understand the study protocol or respond to assessments, 6- More than three times raise of liver enzymes.

**Intervention groups**
Intervention group: Patients are received flexible-dose buprenorphine treatment up to 24 mg/day (12 tablets) plus placebo syrup up to 22 units per day for 24 weeks. Control group: Patients are received flexible-dose methadone treatment up to 110 mg/day (22 cc) plus sublingual placebo up to 12 units for 24 weeks. All active and placebo medications are manufactured by Faran Shimi Pharmaceutical Company.

**Main outcome variables**
Proportion of weekly negative urine test for morphine

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170702034844N7**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **prospective**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

**Registration date**
2020-08-16, 1399/05/26

**Registrant information**

**Name**
Alireza Noroozi

**Name of organization / entity**
Iranian National Center for Addiction Studies (INCAS)

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-09-05, 1399/06/15

**Expected recruitment end date**
2020-11-20, 1399/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of buprenorphine and methadone maintenance treatments in prison: a randomized controlled trial

**Public title**
Comparison of opioid maintenance treatments (OMTs) in prison
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of moderate to severe opioid use disorder based on DSM-5 Continuous consumption of illegal opioids in the past month prior to incarceration Age 18 to 50 years Informed written consent to enter the study Conviction period more than 6 months
**Exclusion criteria:**
Concurrent diagnosis of other substance use disorders (except tobacco) Uncontrolled severe psychiatric disorders including serious suicidality or psychosis based on a study physician's diagnosis Severe and uncontrolled physical conditions including unstable angina, liver failure and a history of myocardial infarction during last month based on physician' s diagnosis and laboratory evaluations Inability to understand the study protocol or respond to study assessments More than three times raise of liver enzymes
**Age**
From **18 years** old to **50 years** old
**Gender**
Male

**Phase**
3
**Groups that have been masked**

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

**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Random codes are created by the person responsible for data randomization using the website www.sealedenvelope.com. Patients are randomly allocated to one of two study arms including sublingual buprenorphine plus placebo syrup and sublingual placebo plus methadone syrup based on random sequence blocks with block size of 4. The codes created by the person responsible for the randomization, are attached to the medications of study groups, and each patient's code is given to the treatment provider in a sealed envelope, consecutively.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Due to the different formulations of buprenorphine and methadone, for blinding, patients in intervention group will receive sublingual buprenorphine tablets and placebo syrup and patients in control group will receive placebo sublingual tablets and methadone syrup. The study is blind, meaning that the patient, therapists, and the statistical analyst will be unaware of the allocation group.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethic Committee of National Institute for Health Research, Tehran University of Medical Sciences
**Street address**
No. 70, North Bozorgmehr St., Vesal Shirazi St., Keshavarz Blvd.
**City**
Tehran
**Province**
Tehran
**Postal code**
1416833481
**Approval date**
2020-06-27, 1399/04/07
**Ethics committee reference number**
IR.TUMS.NIHR.REC.1399.023

## Health conditions studied

### 1

**Description of health condition studied**
Moderate to severe opioids use disorder
**ICD-10 code**
F11.2
**ICD-10 code description**
Opioid dependence

## Primary outcomes

### 1

**Description**
Proportion of negative morphine urine tests
**Timepoint**
Baseline assessment and then weekly during study

**Method of measurement**
Rapid morphine urine test

## Secondary outcomes

### 1

**Description**
Retention in treatment
**Timepoint**
Baseline assessment and then weekly during study
**Method of measurement**
Continuous referrals to receive study medications and physician's visit

## Intervention groups

### 1

**Description**
Intervention group: Sublingual buprenorphine plus placebo syrup. In this study, each unit of sublingual tablet is equal to 2 mg buprenorphine or placebo and each unit of syrup is equal to 5 mg (1 cc) of methadone or placebo. All study active and placebo medications are manufactured by Faran Shimi Pharmaceutical Company. Treatment is initiated with sublingual buprenorphine up to 6 mg/day plus placebo syrup up to 6 cc in the first day. During first week, patient is visited 2 more times and patient' doses are increased up to 8 mg/day of sublingual buprenorphine plus up to 8 cc of placebo syrup, if needed. During weeks 2 to 24, patient is visited on weekly basis and patient's doses are increased up to 24 mg/day of buprenorphine plus 22 cc of placebo syrup, if needed.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Sublingual placebo plus methadone syrup. Treatment is initiated with methadone syrup up to 6 units per day plus sublingual placebo up to 3 units in the first day. During first week, patients are visited 2 more times and patient's doses are increased up to 8 units day of methadone syrup plus 4 units of sublingual placebo, if needed. During weeks 2 to 24, patient is visited on weekly basis and patient's doses are increased up to 22 units of methadone syrup plus up to 12 units of sublingual placebo, if needed.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ghezal Hesar Health Center
**Full name of responsible person**
Dr. Ali Akbar Sedighi
**Street address**
Ghezal Hesar Road, Kianmehr St., Eram Blvd., Mehrshahr
**City**
Karaj
**Province**
Alborz
**Postal code**
۱۹۸۳۸۴۴۵۵۹
**Phone**
+98 26 3326 5027
**Email**
dr.sadighiakha@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Faran Shimi Pharmaceutical Company
**Full name of responsible person**
Ramin Rezaei Tehrani
**Street address**
No 3, Kaveh Dead End, Nirooye Entezami St., Attar St
**City**
Tehran
**Province**
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**Phone**
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**Email**
info@faranshimi.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Faran Shimi Pharmaceutical Company
**Proportion provided by this source**
90
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Industry

### 2

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Mohammadali Sahraian

**Street address**
6th Floor of Central Building of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.
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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**
Tehran University of Medical Sciences

**Proportion provided by this source**
10

**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Alireza Noroozi
**Position**
Psychiatrist
**Latest degree**
Specialist
**Other areas of specialty/work**
Psychiatrics
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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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**Phone**
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a_r_noroozi@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

It is planned to share IPD and report of the clinical study.

**When the data will become available and for how long**

IPD will be shared after completion of the data gathering phase. Report of the clinical study will be finalized at the end of study .

**To whom data/document is available**

Clinical researchers

**Under which criteria data/document could be used**

IPD will be available for researchers who are conducting review studies. Study report will be published as English article.

**From where data/document is obtainable**

Email to the individual who is responsible for scientific inquiries of this project

**What processes are involved for a request to access data/document**

It will be responded after processing within the project team.

**Comments**