Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 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
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Alborz
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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
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Postal code
1994768651
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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1467664961
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vcr@tums.ac.ir

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
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Psychiatrics
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Person responsible for updating data

Contact

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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