

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effectiveness of methadone and temperament-based pharmacotherapy on treatment retention, relapse, and treatment boredom in heroin and methamphetamine dependents

Protocol summary

Study aim

Comparison of the effectiveness of methadone and temperament-based pharmacotherapy on treatment retention, relapse, and treatment boredom in heroin and methamphetamine dependents

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. The rand function of Excel software was used for randomization. All these works will be done with a software called Sealed Envelope. The concept of concealment is the unpredictability of assigning people to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Settings and conduct

This study is a randomized clinical trial with a pre-test and post-test design with a control group with usual treatment. First, 42 people addicted to heroin and methamphetamine are included in the study. These people are divided into two groups using the block randomization method. For six months, each of the two groups at the end of the first, second, third, fourth, and fifth and sixth months of the dependent variables of the treatment, temptation and boredom through The questionnaire will be evaluated and the data will be analyzed through statistical methods in such a way that the statistician will analyze the data of the groups without knowing the type of treatment they received.

Participants/inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study: All dependent patients on heroin and meth-amphetamine Having Novelty seeking temperament Age 18 to 45 years
Exclusion criteria: past history of medical complication after use Antipsychotic past history of Renal and liver disease past history of Heart disease

Intervention groups

group1: Methadon maintenance therapy adjunctive

temprament-based psychopharmacotherapy with 5-10 mg Olanzapine daily group2: Methadon maintenance therapy

Main outcome variables

relapse, boredom

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230914059433N1**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **retrospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Akram Rasti bazoki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

2023-04-04, 1402/01/15

Actual recruitment end date

2023-05-20, 1402/02/30

Trial completion date

2023-11-21, 1402/08/30

Scientific title

Comparison of the effectiveness of methadone and temperament-based pharmacotherapy on treatment retention, relapse, and treatment boredom in heroin and methamphetamine dependents

Public title

Comparison of effect of methadone and methadone adjuvant Olanzapine on treatment in heroin and methamphetamine dependents with Novelty seeking temperament

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study All dependent patients on heroin and meth-amphetamine Having Novelty seeking temperament Age 18 to 45 years Having desire to methadone maintenance treatment

Exclusion criteria:

Having past history of medical complication after use antipsychotic Having past history of Renal and liver disease Having past history of Heart disease

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **42**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 2 blocks will be used to allocate the samples. In this way, by using the block method random number generation software, the randomization sequence will be produced according to the required sample size for two groups. In the beginning, all the modes where 2 letters A and B can be put together in a block of 2 are produced. Then a block will be selected randomly and by placement among the blocks, and the arrangement pattern in that block will be used to allocate the participants. Then this block will be placed in the main container and another block will be selected again. All these works will be done with a software called Sealed Envelope. Using this method,

concealment will also be observed. The concept of concealment is the unpredictability of assigning people to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Single blinded

Blinding description

It only happens when the data analysis is done in such a way that the statistician does not know which group the data belongs to in order to eliminate the bias.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht St

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Province

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3848176341

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.ARAKMU.REC.1401.198

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

methamphetamine dependents

ICD-10 code

T43.625

ICD-10 code description

Adverse effect of amphetamines

2**Description of health condition studied**

heroin dependents

ICD-10 code

T40.1

ICD-10 code description

Poisoning by and adverse effect of heroin

Primary outcomes

1

Description

boredom

Timepoint

6 months

Method of measurement

Boredom questionnaire

2

Description

relapse

Timepoint

6 months

Method of measurement

Urine analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Methadone maintenance therapy adjunctive temperament-based psychopharmacotherapy with 5-10 mg olanzapine orally daily. In this group, people are treated with methadone with a dose determined by the clinician in charge of the clinic based on the national protocol, and this dose is from 40 to 60 mg. In the mornings, this dose is given to him in the form of methadone syrup through the clinic, and along with it, he is treated with 5 mg Olanzapine tablets in each unit of the second generation antipsychotic drugs with a dose of 5 to 10 mg based on the discretion of the relevant psychiatric assistant. It starts from Subhan company and is given to him for one month in the number of 30 to 60 pieces according to the prescribed amount.

Category

Treatment - Drugs

2

Description

Control group: Methadone maintenance therapy. In this group: methadone therapy. This group is treated with methadone syrup at a dose of 40 to 60 mg per day according to the discretion of the clinician in charge of the addiction treatment clinic, and this dose is determined based on the national protocol of methadone maintenance treatment. And for one week, the total dose is given to the patient in the form of syrup, and the patient returns weekly to receive the next doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for studies and treatment of substance use disorder

Full name of responsible person

Dr Rahbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak University of Medical Sciences

Proportion provided by this source

100

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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared.

When the data will become available and for how long

Since 1403

To whom data/document is available

Medical students

Under which criteria data/document could be used

Scientific and therapeutic use is unimpeded.

From where data/document is obtainable

You can contact Dr. Akram Rasti Barzaki located in AmirKabir Arak Medical Center with mobile number 09188487448.

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

3 months

Comments