Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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 meintenance therapy adjuctive temprament-based psychopharmacotherapy with 5-10 mg Olanzapine daily group2: Methadon meintenance 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)

Phone

+98 86 3313 7938

Email address

akrmrastybrzky@gmail.com

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
City
Arak
Province
Markazi
Postal code
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 anlysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Methadon meintenance therapy adjuctive temprament-based psychopharmacotherapy with 5-10 mg olanzapine orally daily .In this group, people are treated with methadone with a dose determined by the clinisiane 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 Elanzapine 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: Methadon meintenance 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 clinisiane 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 It 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
Centerfor studies and treatment of substance use disorder
Full name of responsible person
Dr Rahbari
Street address
Edalat St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Hekmatpo
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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
Arak University of Medical Sciences
Full name of responsible person
Rastibarzoki Akram
Position
Psychiatric assistant
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Email
akrmrastybrzky@gmail.com

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