Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of co-administration of pioglitazone to methamphetamine addict patients therapy regimen on the quality of life and the treatment efficacy.

Protocol summary

Study aim
Comparison of the effect of pioglitazone and placebo on therapeutic efficacy and quality of life in methamphetamine dependent patients.

Design
parallel

Settings and conduct
100 patients between the age range of 20 to 50 due to their addiction to methamphetamine, are hospitalized in Beheshti medical and educational centre of zanjan and/or recourse to clinic of Beheshti medical and educational centre of zanjan, after considering the factors and causes of entry and exit from the study, they are divided into 2 groups randomly. Then, one group will be under treatment with common medicine for their addiction (Control) and for treating 2nd group (Interference) we add Pioglitazone (30mg) for 3 month. After that, during specific intervals the life quality and the rate of response to method are compared in pre and post examination. It is good to mention that, placebo is given to control group with the exact form, size and color of Pioglitazone. Also, quality of life is going to be evaluated by Nottingham's questionnaire and rate of response to the method is going to be evaluated by process of the illness during the study.

Participants/Inclusion and exclusion criteria
inclusion criteria: Methamphetamine dependent patients admitted to zanjan beheshti hospital in the age group of 20 to 50 years. exclusion criteria: 1- chronic medical conditions include diabetes , severe liver disorder & severe heart disorder. 2- pioglitazone contraindications if any.

Intervention groups
Received pioglitazone tablet (30 mg per day)

Main outcome variables
Quality of life, treatment efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190427043389N1**
Registration date: **2019-10-27, 1398/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-27, 1398/08/05**
Update count: **0**

Registration date
2019-10-27, 1398/08/05

Registrant information

Name
Hamed Ghavimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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ghavimih@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-10, 1398/03/20

Expected recruitment end date
2020-01-10, 1398/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of co-administration of pioglitazone to methamphetamine addict patients therapy regimen on the quality of life and the treatment efficacy.

Public title
The effect of pioglitazone on reducing methamphetamine dependence.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Methamphetamine-dependent patients admitted to beheshti hospital in zanjan included in the study. Methamphetamine-dependent patients referred to the clinic of beheshti training center of zanjan in the study. The age range of patients is between 20 to 50 years.
Exclusion criteria:
chronic medical conditions include diabetes , severe liver disorder & severe heart disorder. pioglitazone contraindications if any.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
the clinical trial will be planned in such a way that the participant and the clinical caregiver do not know which of the two control or test groups belongs.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Nxt. Ayatollah mousavi Hospital, Gavazang Blvd. Zanjan, Iran. Postal Code: 45139-56184 P.O.Box: 45195-1338
City
zanjan
Province
Zanjan
Postal code
1338-45195
Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.ZUMS.REC.1398.073

Health conditions studied

1

Description of health condition studied
Methamphetamine dependent patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The effect of pioglitazone on treatment outcome of methamphetamine dependent patients.
Timepoint
three months.
Method of measurement
Based on the nottingham questionnaire.

Secondary outcomes

1

Description
Determination of quality of life in pioglitazone recipient group.
Timepoint
three months.
Method of measurement
Based on the nottingham questionnaire.

Intervention groups

1

Description
Intervention group: received pioglitazone tablet (30 mg per day)
Category
Treatment - Drugs

2

Description
Control group: received placebo tablet

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Medical Center
Full name of responsible person
Dr. Reza Pirzeh
Street address
Zanjan , Ark sq. Dr. Beheshti's Psychiatry Educational-Medicinal Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
Street address
Azadi Square, Central Builtding of Zanjan University of Medical Sciences
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Hamed Ghavimi
Position
academic member
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
zohreh shali

Position
pharmacy student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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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
Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long
three months.

To whom data/document is available
Researchers.

Under which criteria data/document could be used
The person can access the data after requesting and verifying its reliability.

From where data/document is obtainable
Central Library of Medical Sciences University.

What processes are involved for a request to access data/document
The person can access the data after requesting and verifying its reliability.

Comments