

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 zanzan and/or recourse to clinic of Beheshti medical and educational centre of zanzan, 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 zanzan 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)

Phone

+98 24 3347 3635

Email address

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 zanja included in the study. Methamphetamine-dependent patients referred to the clinic of beheshti training center of zanja 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 Zanja University of Medical Sciences

Street address

Nxt. Ayatollah mousavi Hospital, Gavazang Blvd. Zanja, Iran. Postal Code: 45139-56184 P.O.Box: 45195-1338

City

zanjan

Province

Zanja

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 centers1**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 sources1**Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Azadi Square, Central Building 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 scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

zohreh shali

Position

pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

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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