

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of adding pioglitazone to the regimen of opium-dependent & heroin-dependent patients on quality of life and treatment efficacy.

Protocol summary

Study aim

The effect of adding pioglitazone to the regimen of opium-dependent & heroin-dependent patients on quality of life and treatment efficacy.

Design

controlled clinical trial with intervention and placebo groups

Settings and conduct

100 patients between the age range of 20 to 50 due to their addiction to opium & heroin, are hospitalized in Beheshti medical and educational centre of zanjaan and/or recourse to clinic of Beheshti medical and educational centre of zanjaan, 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: opium-dependent & heroin-dependent patients admitted to zanjaan 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: **IRCT20190427043389N2**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

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

2019-11-15, 1398/08/24

Expected recruitment end date

2020-06-13, 1399/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding pioglitazone to the regimen of opium-dependent & heroin-dependent patients on quality of life and treatment efficacy.

Public title

The effect of pioglitazone on reducing opioid and heroin dependence.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Opium and heroin-dependent patients admitted to Shahid Beheshti Hospital in Zanjan are included in the study. Opium and heroin-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 (Block size=4)

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.

City

zanjan

Province

Zanjan

Postal code

56184- 45139

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.ZUMS.REC.1398.340

Health conditions studied

1

Description of health condition studied

Opiate and heroin-dependent patients

ICD-10 code

F11.1

ICD-10 code description

Opioid abuse

Primary outcomes

1

Description

Evaluation of the effect of pioglitazone on treatment outcome in opium and heroin 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) for three months

Category

Treatment - Drugs

2

Description

Control group: received placebo tablet for three months

Category
Placebo

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

City

zanjan

Province

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15788-45136

Phone

+98 24 3354 2404

Email

ghavimih@zums.a.ir

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 Building of Zanjan University
of Medical Sciences

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Email

shoghli@zums.ac.ir

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

60

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

2

Sponsor

Name of organization / entity

Zahravi Pharmaceutical Company

Full name of responsible person

Dr. Hamed Hamishehkar

Street address

19th kilometer of tabriz-tehran's pathway , serum
daroo street

City

Tabriz

Province

East Azarbaijan

Postal code

5167113675

Phone

+98 41 3630 9401

Fax

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Email

info@zahravipharma.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahravi Pharmaceutical Company

Proportion provided by this source

40

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

Industry

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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sajad Ghasemi

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