

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of zinc supplementation (Zn) on metabolic profile and expression of IL10, PPAR γ , NRF2 genes in methadone maintenance patients

Protocol summary

Study aim

The effect of zinc supplementation (Zn) on metabolic profile and expression of IL10, PPAR γ , NRF2 genes in methadone maintenance patients

Design

Accidental clinical trial of two concours (both patients and researchers) in parallel.

Settings and conduct

Sample size and study population: 60 patients undergoing treatment with qualified methadone and referred to the Addiction Treatment Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study.

Participants/Inclusion and exclusion criteria

Criteria for entry into the study: Patients undergoing methadone maintenance therapy will enter the study in the age range of 30 to 60 years. Criteria for withdrawal from the study: Lack of willingness to cooperate, zinc consumption in the three months before the intervention, specific disease, positive urine test for methamphetamine and cannabis

Intervention groups

Patients will be divided into zinc (n = 30) or placebo (n = 30) for supplementation. Zinc and placebo supplements are similar in shape and size.

Main outcome variables

Anxiety and depression (primary outcome) and inflammatory factors, oxidative stress, cholesterol, triglycerides, HDL, insulin sensitivity, insulin resistance, fasting blood sugar, serum levels (secondary outcome) will be measured at the beginning and end of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048050N1**

Registration date: **2020-09-08, 1399/06/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-08, 1399/06/18**

Update count: **0**

Registration date

2020-09-08, 1399/06/18

Registrant information

Name

Azam Ghsemineghad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc supplementation (Zn) on metabolic profile and expression of IL10, PPAR γ , NRF2 genes in

methadone maintenance patients

Public title

Evaluation of the effect of zinc supplementation (Zn) in patients receiving methadone maintenance treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients treated with methadone maintenance in the age range of 30 to 60 years

Exclusion criteria:

Positive urinary test for morphine, methamphetamine and cannabis Do not have a specific disease Zinc consumption in the last 3 months High blood pressure Consumption of psychiatric and neurological drugs during the study Digestive problems and side effects of zinc consumption Consumption of iron supplements

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

How to randomize with a simple method and use random numbers created by computer software (Stat Trek software) will be done. In this method, the computer selects random numbers. By considering numbers for two groups, randomization is done. For example, even numbers will be in the intervention group and odd numbers will be in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo has been used for blinding. Researchers and blind patients will be trained by a staff member until the final analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences Ethics Committee

Street address

Ghotbe Ravandi Boulevard, Kashan

City

kashan

Province

Isfahan

Postal code

8814187159

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.134

Health conditions studied

1

Description of health condition studied

addiction

ICD-10 code

F17.210

ICD-10 code description

مواد مخدر 'سیگار' اعتیاد

Primary outcomes

1

Description

Anxiety

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Beck Depression Inventory

2

Description

Depression

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

Total serum cholesterol

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Clinical laboratory kit

2

Description

HDL-C Serum

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Clinical laboratory kit

3

Description

Serum triglyceride

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Clinical laboratory kit

4

Description

Fasting blood sugar

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Enzymatic

5

Description

Insulin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Eliza

6

Description

Insulin sensitivity

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Formula calculation

7

Description

Insulin resistance

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Formula calculation

8

Description

Total Glutathione

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

9

Description

Malone di aldehyde

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

10

Description

Expressed levels of PPAR- γ

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

PCR

11

Description

Expressed levels of IL-10

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

PCR

12

Description

Expressed levels of NRF2

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: 30 mg International Zinc Supplement (Jalinous), orally daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Jalinous), every day of the week, orally for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Soltan Mirahmad Clinic

Full name of responsible person

Amir Ghaderi

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Shahid Motahari Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Azam Ghasemi Nejad

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available