

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effectiveness of zinc supplementation on the possibility of relapse of anxiety and depression in opioid dependent patients under methadone maintenance treatment.

#### Protocol summary

##### Study aim

Evaluating the effectiveness of zinc supplementation on the possibility of recurrence of anxiety and depression in opioid-dependent patients undergoing methadone maintenance treatment

##### Design

This study is a clinical trial with a control group, with parallel, double-blind, randomized groups with 38 patients participating in each group. Random allocation software will be used for randomization.

##### Settings and conduct

This study will be conducted on methadone treated patients referred to Ahvaz Golestan Hospital. Patients do not know the type of medicine received. Also, the evaluator is unaware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

Included criteria: age 18 to 60 years; receiving methadone as the only treatment protocol; Diagnosis of substance abuse disorder based on DSM-V diagnostic criteria Exclusion criteria: History of allergy to compounds containing zinc; the use of compounds containing zinc and other medicinal supplements before the intervention and study; Having harmful thoughts to yourself and others

##### Intervention groups

Patients in the intervention group will receive 220 mg zinc sulfate capsules every other day. In control group, patients will receive placebo two days apart.

##### Main outcome variables

Anxiety; Depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160417027437N3**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

##### Registration date

2023-06-18, 1402/03/28

##### Registrant information

###### Name

Amirali Moghaddam Sadegh

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3374 3038

###### Email address

moghaddam.a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effectiveness of zinc supplementation on the possibility of relapse of anxiety and depression in opioid dependent patients under methadone

maintenance treatment.

### Public title

Effectiveness of zinc supplementation on the possibility of recurrence of anxiety and depression in opioid dependent patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 18 to 60 years Diagnosis of substance abuse disorder based on DSM-V diagnostic criteria Receiving methadone as the only treatment protocol

#### Exclusion criteria:

History of allergy to compounds containing zinc The use of compounds containing zinc and other medicinal supplements before intervention and study Having harmful thoughts to yourself and others

### Age

From **18 years** old to **60 months** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **76**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be done based on the method of random block permutations. Random sequence generation software is used, which refers to the method used to perform a random sequence on the participants in the study, so that the assigned group is not known before assigning the individual. By using sealed opaque mail envelopes with a random sequence, each of the generated random sequences is recorded on a card and the cards are placed inside the mail envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups. According to that, there are 2 treatments, for every block a different random order will be prepared. Random table was used as the randomization tool.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, the project manager and the patient are unaware of which of the two groups will receive which drug or placebo. Medicines and placebos will be similar in terms of shape, color, smell and taste.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz, Golestan St., Farvardin Blvd., Jundishapur University of Medical Sciences, Ahvaz

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

#### Approval date

2023-05-27, 1402/03/06

#### Ethics committee reference number

IR.AJUMS.REC.1402.119

## Health conditions studied

### 1

#### Description of health condition studied

Patients dependent on opioids

#### ICD-10 code

F11

#### ICD-10 code description

Opioid related disorders

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before the intervention, one month and three months after the intervention

#### Method of measurement

Spielberger questionnaire

### 2

#### Description

Depression

#### Timepoint

Before the intervention, one month and three months after the intervention

#### Method of measurement

Beck depression questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In addition to methadone as the main treatment, patients in the intervention group will receive 220 mg zinc sulfate capsules every other day for three months. The dose of this capsule will not change during the study period. This pill will be prepared from Aria Pharmaceuticals.

### Category

Treatment - Drugs

2

### Description

Control group: In addition to methadone as the main treatment, patients in this group will receive placebo capsules every other day for three months. Medicines and placebos will be similar in terms of shape, color, smell, and taste. This pill will be prepared under the supervision of the Faculty of Pharmacy of Ahvaz University of Medical Sciences.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ahvaz Golestan Hospital

#### Full name of responsible person

Simin Ghafari

#### Street address

Ahvaz Golestan Hospital, Golestan Ave, Ahvaz

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Ahvaz

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6135715794

#### Phone

+98 61 3374 3038

#### Email

m.simin.02@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

### Full name of responsible person

Mehrnoosh Zakerkish

### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Farvardin Blvd, Golestan Ave, Ahvaz Ahvaz

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zakerkish.m@ajums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

#### Full name of responsible person

Amir Ali Moghadam Sadegh

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Psychiatrics

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Golestan hospital, Farvardin Blvd, Golestan Ave,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Amir Ali Moghadam Sadegh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

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Resident

**Latest degree**

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**Other areas of specialty/work**

Psychiatrics

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**Email**

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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