Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Amirali Moghaddam Sadegh

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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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
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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

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Ahvaz Golestan Hospital,Golestan Ave, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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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