

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of zinc supplements on the oxidative stress and reduction of withdrawal symptoms in opioid addicts in the withdrawal syndrome

#### Protocol summary

##### Study aim

The effect of zinc supplements on the oxidative stress and reduction of withdrawal symptoms in opioid addicts in the withdrawal syndrome

##### Design

This study is a phase 3 clinical trial with control group, with parallel groups, three blind, randomized, with a volume of 40 samples.

##### Settings and conduct

After diagnostic and clinical interview by psychiatrist in psychiatry department as well as diagnostic criteria for drug dependence based on DSM-5 at Hamadan Sina Farshchian Hospital, peripheral blood of studied subjects after obtaining consen, were taken to measurement of serum antioxidant capacity, serum level of malondialdehyde, serum thiol groups, activity of glutathione peroxidase and superoxide dismutase enzymes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include opioid use for two years or more, hospitalization for up to one week from the time of withdrawal, no medication without clinical expertise, absence of acute and chronic inflammatory diseases, and any acute or chronic infections. Other and no mention of AIDS, hepatitis and diabetes.

##### Intervention groups

In general, two intervention and control groups will participate in this study. Subjects in the intervention group use 30 mg zinc tablets. In the control group, a placebo zinc pill form and color is used.

##### Main outcome variables

Oxidative stress factors, reduction of withdrawal symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190811044513N1**

Registration date: **2019-09-11, 1398/06/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-11, 1398/06/20**

Update count: **0**

##### Registration date

2019-09-11, 1398/06/20

##### Registrant information

###### Name

Reza Gheytsi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3252 0182

###### Email address

r.gheytsi@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-22, 1398/05/31

##### 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 supplements on the oxidative stress and reduction of withdrawal symptoms in opioid addicts in the withdrawal syndrome

##### Public title

The effect of zinc supplements on the oxidative stress and reduction of withdrawal symptoms in opioid addicts in the withdrawal syndrome

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Opioid use for two years and more Admission within a maximum of one week from the time of withdrawal Not taking medications away from the specialist opinion Absence of acute and chronic inflammatory diseases and any other acute or chronic infections Lack of AIDS, hepatitis and diabetes

##### **Exclusion criteria:**

Re-consuming by people before sampling Use of drugs that have an effect on inflammation and oxidative stress Getting any disease during research Attempted suicide or a history of it during the past year

#### **Age**

From **18 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### **Sample size**

Target sample size: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

For this purpose we will use quadratic random blocks method. For this purpose, we provide four sheets of paper for each drug and placebo group separately. We write on two sheets of letter A (intervention group) and on the other two sheets of letter C (comparison group). Mix the sheets together and place in a drawer. By referring to each eligible patient, one sheet was randomly drawn and the A or C sheet was drawn according to one of the two groups (zinc recipient) and control group Will be allocated. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets have been drawn. Once the four sheets have been randomly pulled out, all the sheets are returned to the drawer and the procedure will be repeated for the next four patients until the desired sample size is reached.

#### **Blinding (investigator's opinion)**

Triple blinded

#### **Blinding description**

Patients in the intervention group received 30 mg zinc pills without awareness. The other group uses medication that is a form and color with zinc tablets. Also, the treating physician who will examine patients will not be aware of the type of medication used for patients. In addition, the statistical analyst will not be aware of the drug code used. Therefore, this study will

be a triple blind.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

###### **Street address**

Shahid Fahmide Ave, Hamadan University of Medical Sciences, Faculty of Pharmacy

###### **City**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838678

##### **Approval date**

2019-07-05, 1398/04/14

##### **Ethics committee reference number**

IR.UMSHA.REC.1398.306

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

People with Opioid Addiction

##### **ICD-10 code**

Z.81-4

##### **ICD-10 code description**

Family history of other substance abuse

### **Primary outcomes**

#### 1

##### **Description**

Oxidative stress factors, reduction of withdrawal symptoms

##### **Timepoint**

At the beginning and end of the study

##### **Method of measurement**

Serum level measurement by using kits

### **Secondary outcomes**

#### 1

##### **Description**

Antioxidant capacity of serum

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Colorimetric method

**2**

**Description**

Lipid Peroxidation Index

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Colorimetric method

**3**

**Description**

Thiol groups index

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Colorimetric method

**4**

**Description**

Enzymatic activity of glutathione peroxidase

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Colorimetric method

**5**

**Description**

Enzymatic activity of superoxide dismutase

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Colorimetric method

**6**

**Description**

Evaluation of withdrawal symptoms

**Timepoint**

At the beginning and end of the study

**Method of measurement**

COWS questionnaire

**Intervention groups**

**1**

**Description**

Intervention group: Opioid addicts who use 30 mg zinc tablets from the US company Naturemade. The pill is given to each patient during one month and one pill for each day. It is recommended to take the pill at night and after dinner to better absorb and reduce the gastrointestinal side effects. Blood sampling was performed once before the intervention and once after

the intervention.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: The control group is opioid addicts who use a placebo that completely similar to zinc tablets during one month and one pill for each day. This placebo was made at the Faculty of Pharmacy, Hamadan University of Medical Sciences. It is recommended to be taken at night and after dinner in order to better absorb and reduce the gastrointestinal side effects. Blood sampling was performed once before the intervention and once after the intervention.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Farshchian Hospital

**Full name of responsible person**

Ali Hasanalizadeh

**Street address**

Mirzadeh Eshghi Ave, Farshchian Hospital

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6516848741

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farsh\_hamedan@umsha.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Behavioral Disorders and Substance Abuse Research Center

**Street address**

Behavioral Disorders and Substance Abuse Research Center, Farshchian Psychiatric Center, Mirzadeh Eshghi St, Hamadan, Iran

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bsarc@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Ali Hasanalizadeh

**Position**

Phd student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

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Associate professor

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Ph.D.

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**Person responsible for updating data**

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**Position**

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**Latest degree**

A Level or less

**Other areas of specialty/work**

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alizadeh01996@gmail.com

**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