Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Gheytasi
Name of organization / entity
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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 HamadanUniversity of Medical Sciences

Street address

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

City

Hamadan

Province

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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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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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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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

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Sara Ataei

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Latest degree

Ph.D.

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Person responsible for updating data

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Other areas of specialty/work

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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