

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluating the effect of Oxytocin with Zinc sulphate on the withdrawal symptoms, craving, anxiety and reproductive indices in opiates addicted men under Methadone Maintenance Therapy

#### Protocol summary

##### Study aim

Evaluating the effect of Oxytocin with Zinc sulphate on the withdrawal symptoms, craving, anxiety and reproductive indices in opiates addicted men under Methadone Maintenance Therapy

##### Design

In the outpatient treatment center, oxytocin nasal spray and normal saline nasal spray will have similar containers. Zinc sulfate and zinc sulfate placebo will have identical capsules. so that if you don't refer to it, you can't understand which is real and which is placebo. The therapist and the patient will be unaware of the actual contents of the containers.

##### Settings and conduct

.At the outpatient treatment center, the people participating in the intervention will receive a coded package that, based on randomization, they have the possibility of being placed in the control or treatment group (coded by a third party), which the therapist and the patient seeker will not be aware of its actual content. They are aware that ultimately the code will determine whether the person received the actual treatment or a placebo

##### Participants/Inclusion and exclusion criteria

Entry requirements: According to the DSM-5, a person must qualify for opioid dependence be treated with methadone maintenance Have written consent Age between 20 and 50 years and should be literate Non-entry conditions: A person with suicidal thoughts, a history of any kind of blood, glandular, heart, lung, kidney disease, drug sensitivity, diabetes, major depressive disorder Individuals receiving glucocorticoid, serotonergic, or other antidepressant therapy

##### Intervention groups

The intervention group includes MMT patients who will receive oxytocin nasal spray and zinc sulfate capsules The control group includes MMT patients who will receive

saline nasal spray and zinc sulfate capsule placebo

##### Main outcome variables

oxytocin; zinc; withdrawal ; Craving Stress; anxiety; depression; testosterone; spermogram

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221022056266N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

##### Registration date

2022-12-26, 1401/10/05

##### Registrant information

##### Name

naser mirzareei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3341 2593

##### Email address

nasermirzaie52@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-05-21, 1402/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluating the effect of Oxytocin with Zinc sulphate on the withdrawal symptoms, craving, anxiety and reproductive indices in opiates addicted men under Methadone Maintenance Therapy

**Public title**  
The effect of Oxytocin with Zinc supplement in treating opiates addiction and improving fertility in Men

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
According to the DSM-5, a person must qualify for opioid dependence The patient is being treated with methadone maintenance and is stabilized on it The patient must give written consent to participate in the intervention People participating in the intervention must be male and between 20 and 50 years old and must be literate  
**Exclusion criteria:**  
Having suicidal thoughts History of any kind of blood disease, glandular disease, heart disease, lung disease, kidney disease, drug sensitivity, diabetes People with major depressive disorder People receiving glucocorticoid treatment in the last month People receiving serotonergic therapy or other antidepressants

**Age**  
From **20 years** old to **50 years** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **40**

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

**Randomization description**  
First, using the Random number generation plugin in Excel software, a table of random numbers from 1 to 40 is prepared in a non-sequential and scattered manner, and intervention and control are done by assigning numbers to two groups of 20 people. The randomization process is done by the study consultant, and the clinical researchers do not know about the randomization process, and only randomized codes from 1 to 40 will be provided to them.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Researchers are given a table of

coded numbers in advance, and patients are included in the study in the order of the numbers in the table. Therefore, the present study is double-blind. Oxytocin spray, zinc sulfate capsule, and placebo are both identical in shape, color, and size, and are delivered to the patient in a package.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

##### Street address

Zanjan University of Medical Sciences , Azadi Square, Zanjan, Iran

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4515613191

#### Approval date

2022-06-21, 1401/03/31

#### Ethics committee reference number

IR.ZUMS.REC.1401.096

## Health conditions studied

### 1

#### Description of health condition studied

Dependence on opioids

#### ICD-10 code

F00-F99

#### ICD-10 code description

withdrawal symptoms, Craving, Anxiety, Opiate Addicted men, Fertility

## Primary outcomes

### 1

#### Description

Oxytocin

#### Timepoint

Before and after the intervention and two months later for follow-up

#### Method of measurement

Hormonology

## 2

### **Description**

zinc

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Measurement of zinc level in blood

## **Secondary outcomes**

## 1

### **Description**

Clinical Opiate Withdrawal Scale

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Through the checklist for withdrawal symptoms: For each item, circle the number that best describes the patient's signs or symptom.

## 2

### **Description**

Craving

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Desire for Drug Questionnaire

## 3

### **Description**

Stress

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Depression- Anxiety- Stress Scale

## 4

### **Description**

Anxiety

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Depression- Anxiety- Stress Scale

## 5

### **Description**

Depression

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Depression- Anxiety- Stress Scale

## 6

### **Description**

Testosterone

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

Hormonology

## 7

### **Description**

Spermogram

### **Timepoint**

Before and after the intervention and two months later for follow-up

### **Method of measurement**

In the Spermogram, two characteristics of semen are considered: 1- Macroscopic characteristics 2- Microscopic characteristics Macroscopic characteristics of semen including color, transparency, concentration of hydrogen ions or pH, volume, duration of closeness, fluidity and viscosity are examined. take The microscopic characteristics of semen include motility, sperm count, viability, sperm morphology, white and red blood cells, and the quality of fructose levels in semen.

## **Intervention groups**

## 1

### **Description**

Control group: A sample of 20 people will be the control group, who will receive oxytocin spray placebo and zinc sulfate placebo for fourteen days.

### **Category**

Placebo

## 2

### **Description**

Intervention group: A sample of twenty people will be the intervention group, who will receive oxytocin nasal spray and zinc sulfate capsules for fourteen days. The intervention group will receive 40 international units of oxytocin nasal spray and one 220 mg zinc sulfate capsule daily.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Dr. Beheshti Hospital

#### **Full name of responsible person**

Nasser Mirzaei

#### **Street address**

Dr. Beheshti Hospital , Arg Square

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[https://beheshti.zums.ac.ir/index.php?slc\\_lang=fa&sid=306](https://beheshti.zums.ac.ir/index.php?slc_lang=fa&sid=306)

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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[https://zums.ac.ir/index.php?slc\\_lang=en&sid=266](https://zums.ac.ir/index.php?slc_lang=en&sid=266)  
**Grant name**  
From the budget line of the research project of Zanjan University of Medical Sciences  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Zanjan 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**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Ehsan Sabouri  
**Position**  
University professor  
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Ph.D.  
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## Person responsible for scientific inquiries

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

The data should be such that they do not need additional explanation

**When the data will become available and for how long**

Access starts six months after results are published

**To whom data/document is available**

The data will be available only to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

It will be available to researchers in academic and scientific institutions for the purpose of research development.

**From where data/document is obtainable**

A journal that works in the field of addiction and will accept the publication of research articles

**What processes are involved for a request to access data/document**

According to the rules of the journal

**Comments**