Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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 mirzarei

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
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Web page address
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
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Person responsible for updating data

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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