

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of nasal oxytocin spray efficacy in scales of the withdrawal sign and craving and relapse When cutting methadone in opioids addicted people that have received methadone .

Protocol summary

Study aim

Evaluation of oxytocin spray efficacy in scales of the withdrawal sign, craving and relapse When cutting methadone in opioid addicted people

Design

in a randomized, double-blind, clinical trial With help of random sequencing software, we divide peoples into 4 groups with using block randomization. 60 patients were randomly divided into 4 groups and The efficacy of oxytocin Prescription along with group activities is evaluated for up to 4 months.

Settings and conduct

At an outpatient addiction treatment center, an expert will label oxytocin or saline solution in similar containers. He then gives them to the therapist who is with the patients. The therapist and the patient will be unaware of the actual contents of the dishes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Daily use of 10 to 100 mg of methadone for longer than 6 months.They tend to cut it but cannot ; These people are all men and between 18 and 55 years old. Exclusion criteria: history of Seizure - Head injury history recently - drug abuse in the past 3 months - Severe suicidal thoughts with severe depression - Severe neurological disorders - Acute cardiac abnormalities - psychotic disorders- Severe allergic disease

Intervention groups

Intervention group includes patients treated with MMT.The intervention is: 1. Administeration of oxytocin 2.group activities. The control group includes patients treated with MMT.intervention is 1-nasal saline and 2-individual interventions.We compared the individuals in the four factorial groups . - Prescribing nasal: 1 oxytocin individually. 2. placebo individually . 3. placebo in group. 4. oxytocin in group

Main outcome variables

craving, withdrawal symptoms, urinary morphine and methadone tests, persistence on Participation in grouptherapy , beck anxiety and depression scale, cortisol and oxytocin serum levels , The rate of blood flow to brain regions in fmri

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191003044971N1**

Registration date: **2019-11-30, 1398/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

Registration date

2019-11-30, 1398/09/09

Registrant information

Name

shahram naderi mazjin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 1372

Email address

shahramnadery@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of nasal oxytocin spray efficacy in scales of the withdrawal sign and craving and relapse When cutting methadone in opioids addicted people that have received methadone .

Public title

Evaluation of nasal oxytocin spray efficacy in cutting methadone in opioids addicted people that have received methadone .

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

These people are all men. They are between 18 and 55 years old. They have a history of drug addiction, with the drug being discontinued and replaced with methadone. The amount of methadone consumed is between 10 and 100 mg They have been on methadone maintenance therapy for longer than 6 months now on his own offer Or, as the need arises (example with travel abroad, employment or marriage)he wants to cut off methadone consumption. But despite the high tendency to Interruption of methadone has not been able to reduce methadone levels in 14 days Recently, his methadone dose has not changed. This pations were no positive morphine test for the past 3 months.

Exclusion criteria:

There is a history of seizures Recent history of brain injury drug abuse in the past 3 months Severe suicidal thoughts with severe depression Severe allergic disease Severe neurological disorders, especially if it causes increased risk of seizure Acute cardiac abnormalities present History of psychotic disorders acute vascular disorders

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software, which is part of the random sequence generation software, We randomly divided the subjects into 4 groups by block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The monitoring expert will label oxytocin nasal spray or sodium chloride solution in similar containers. He then delivers them to a therapist who will be with the patients. The therapist and the patient will be unaware of the actual contents of the containers.

Placebo

Used

Assignment

Factorial

Other design features

In this study, 60 patients were randomly assigned into 4 groups of 15 each and the efficacy of group oxytocin Prescription was evaluated.In addition, the efficacy of Prescription of oxytocin or placebo is compared with fmri.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of tehran University of Medical Sciences

Street address

No.7, blind alley2,Navid alley, Nejatollahi st.karimkhanzand st.

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Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3933

Health conditions studied**1****Description of health condition studied**

drug addiction

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes**1****Description**

craving of opioids abuse

Timepoint

Days 2, 3 and 4 after discontinuing methadone

Method of measurement

Self-report based on the ten-point Likert scale

2

Description

withdrawal sign of cutting of methadone

Timepoint

Days 2, 3 and 4 after discontinuing methadone

Method of measurement

Self-report based on the ten-point Likert scale

3

Description

Morphine and methadone test result

Timepoint

At the end of each week after discontinuing methadone until the end of the month 4

Method of measurement

Take a morphine and methadone test

Secondary outcomes

1

Description

Participate in group therapy

Timepoint

End of each week until the end of the fourth month after discontinuing methadone

Method of measurement

Registration of people attending grouptherapy each week by therapist

2

Description

Beck Depression and Anxiety Inventory Scale

Timepoint

Once on the first day and on the fifth to tenth day after discontinuing methadone

Method of measurement

Filling and Calculating Score of Beck Depression or Anxiety Inventory

3

Description

calculation of Serum levels of cortisol and oxytocin

Timepoint

Once at the beginning of the first day and the second time at the fourth day after discontinuing methadone

Method of measurement

take of Blood sampling and measurement of cortisol and oxytocin levels by Kit Elisa

4

Description

Comparison of the effects of oxytocin use in group versus placebo use in group in reducing or increasing the activity of different parts of the brain

Timepoint

Once at the beginning of the first day and the second time at the fourth or fifth day after discontinuing methadone

Method of measurement

Getting fmri brain

Intervention groups

1

Description

Intervention group: Take oxytocin nasal sprays two puffs every 6 hours in groups with targeted group activities

Category

Treatment - Drugs

2

Description

Intervention group: Taking placebo nasal spray 2 puffs every 6 hours in groups with targeted group activities

Category

Treatment - Drugs

3

Description

Intervention group: Take oxytocin nasal spray 2 puffs every 6 hours individually

Category

Treatment - Drugs

4

Description

Control group: Take placebo nasal spray 2 puffs every 6 hours individually

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Addiction Treatment Center of ahang

Full name of responsible person

shahram naderi mazjin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

shahram naderi mazjin

Position

student of phd

Latest degree

Medical doctor

Other areas of specialty/work

addiction

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Person responsible for scientific inquiries

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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