Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

To determine the effect of Oxytocin in compared with placebo on craving; withdrawal and stress response in heroin dependents.

Protocol summary

Summary

The present clinical trial is a randomized, double blind, placebo-controlled study. It is designed to study the possible effects of Oxytocin nasal spray on withdrawal syndrome, craving and response to stress in heroin dependents in the beginning of the treatment period. The people will be divided randomly into two groups based Permuted Block Randomization methods on 4 and 6 blocked. According to the double-blind method, the intervention group will receive a random package, containing oxytocin spray ;and the control group will receive the placebo in similar package and special code. The study will be conducted on two randomized groups of patients (male and female) including 25 people aged between 20 to 60 who meet DSM-IV criteria for heroin dependency in their beginning of treatment. Patients in the first group (drug takers) will receive Oxytocin nasal spray (40 IUs) and the control group will receive placebo (saline) only for one time. Duration of the study on each patient is 6 hours and patients would be excluded from the study if they show positive urine tests of abuse of any narcotic drugs or stimulants. Symptoms of heroin dependence (such as craving, withdrawal syndrome, response to stress) will be measured before and after Oxytocin nasal spray administration and getting stress (viewing some pictures with neutral content or illegal drug or its tools and emotional pictures). Craving will be measured by the heroin Craving questionnaire, Go/No-Go task and Stroop task. Withdrawal symptoms will be measured by the Opiate withdrawal symptoms checklist. Stress will be measured by measuring blood Cortisol and the check list for stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103024792N1**

Registration date: **2016-06-12, 1395/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Mina Moeini

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To determine the effect of Oxytocin in compared with placebo on craving; withdrawal and stress response in heroin dependents.

Public title

Evaluation of Oxytocin,s effect in comparison with placebo on craving; withdrawal and stress response due to heroin.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Subjects must meet DSM-IV criteria for current heroin dependence (within the past six months). Subjects must be at the beginning of treatment period and must abstain from heroin for at least three days prior to testing. patients willing to participate in the intervention- The age range of subjects must be between 20 to 60 years old. Subjects must be literate. Exclusion Criteria : Women who are pregnant, nursing or of childbearing potential and positive of pregnancy test. Subjects with evidence of or a history of significant hematological, endocrine, cardiovascular, pulmonary, renal, drug allergy or neurological disease including diabetes, as these conditions may affect physiological/subjective responses. Subjects with Addison's disease, Cushing's disease or other diseases of the adrenal cortex likely to affect hormonal/neuroendocrine status. Subjects with current major depressive disorder, bipolar or post-traumatic stress disorder as these disorders are associated with characteristic changes in stress response. Subjects receiving synthetic glucocorticoid therapy, any exogenous steroid therapy within one month of test session. Subjects taking any psychotropic medications, including SSRI's or other antidepressants, opiates or opiate antagonists as these medicines may affect the test response. Subjects with any acute illness or fever. - positive urine tests indicating abuse of any abuse or stimulant.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Double blind is related to two groups: subject and investigator

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Kashan University of Medical Sciences

Street address

School of Medicine , Kashan University of Medical Sciences ,Kashan

City

Kashan

Postal code

Approval date

2015-10-21, 1394/07/29

Ethics committee reference number

IR. KAUMS. REC. 1394. 87

Health conditions studied

1

Description of health condition studied

Withdrawal syndrome

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

2

Description of health condition studied

Craving

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

clinical symptom of withdrawal syndrome of heroin

Timepoint

before and after receiving oxytocin

Method of measurement

clinical opioid withdrawal scale

Secondary outcomes

1

Description

clinical opiod craving

Timepoint

before and after receiving oxytocin

Method of measurement

clinical opioid craving scale

Intervention groups

1

Description
Group1: one time 40 IUs intranasal Oxytocin(Pitocin) from NOVARTIS company
Category
Treatment - Drugs

2

Description
Group2 : one time 40 IUs intranasal saline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Khaboshani center
Full name of responsible person
Ali Amini
Street address
Shahid Khaboshani center. West jelvan Ave. Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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School of Medicine .Kashan University of Medical Sciences .
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Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty