

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The Effect of oxytocin on clinical signs, ACTH & cortisol levels and methamphetamine craving in matrix maintenance treatment

Protocol summary

Study aim

The aim of study is to evaluate the efficacy of oxytocin in treating methamphetamine dependency.

Design

In this research, 50 eligible patients with methamphetamine dependency diagnosis according to DSM-IV criteria will be included. Participants will randomly be divided into two intervention and control groups and each participant will be assigned a code.

Settings and conduct

Among patients with methamphetamine abuse referred to Noor Hospital affiliated to Isfahan University of Medical Sciences, 50 patients will be selected according to inclusion and exclusion criteria. Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: methamphetamine dependency assessed by the substance abuse section of the Structured Clinical Interview of DSM-IV; Patients with Matrix Model treatment; aged 18 to 65 years Exclusion Criteria: Suicide attempts within the past 12 months; Unwillingness to cooperate in study.

Intervention groups

The first group will receive oxytocin spray 40IU daily for 28 days. The second group will receive placebo for 28 days.

Main outcome variables

Desire for methamphetamine with CCQ-Brief Questionnaire, Depression with Beck Depression Inventory (BDI) and Anxiety with Beck Anxiety Inventory (BAI) will be completed questionnaire weekly. ACTH level and Cortisol also will be evaluated at study baseline, middle and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171129037673N1**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

Abbas Azadbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3338 1066

Email address

azadbakht-a@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of oxytocin on clinical signs, ACTH & cortisol levels and methamphetamine craving in matrix maintenance treatment

Public title

The Effect of oxytocin on clinical signs, ACTH & cortisol levels and methamphetamine craving in matrix maintenance treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years old Male Methamphetamine dependency as assessed by the substance abuse section of the Structured Clinical Interview of DSM-IV Being at the Matrix Model of treatment. Seeking treatment for methamphetamine use Patients willing to participate in the intervention

Exclusion criteria:

Suicide attempts within the past 12 months; suicidal ideas or psychotic symptoms in the past 6 months determined by a study team physician Current opioid, alcohol or sedative physical dependence or cocaine dependence Major cardiovascular disorder Abnormal liver function Having severe psychotic disorders Metabolic diseases such as diabetes Neurological diseases Positive urine tests indicating abuse of any substance or stimulant Unwillingness to participate in the study

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study group. Use of Placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kashan univetsity of medical sciences

Street address

No.8187695895 , East shahidan Ave.

City

isfahan

Province

Isfahan

Postal code

8187695895

Approval date

2017-11-17, 1396/08/26

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.62

Health conditions studied

1

Description of health condition studied

Drug abuse

ICD-10 code

Z71.5

ICD-10 code description

Drug abuse counseling and surveillance

Primary outcomes

1

Description

Measure of desire for methamphetamine

Timepoint

Complete questionnaire weekly

Method of measurement

CCQ-Brief Questionnaire

2

Description

Depression beck score

Timepoint

Complete questionnaire weekly

Method of measurement

Questionnaire

3

Description

Anxiety beck score

Timepoint

Complete questionnaire weekly

Method of measurement

Questionnaire

4

Description

ACTH level in the blood plasma

Timepoint

Before, middle and end of study

Method of measurement

Blood screening

5

Description

Cortisol level in the blood plasma

Timepoint

Before, middle and end of study

Method of measurement

Blood screening

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will receive oxytocin nasal spray, 10IU/spray, twice a day until 28 days. (One dose in each nostril (40IU daily))

Category

Treatment - Drugs

2

Description

Control group: One time 40 IU intranasal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor hospital

Full name of responsible person

Abbas Azadbakht

Street address

Ostandari Ave.

City

Isfahan

Province

Isfahan

Postal code

8187695895

Phone

+98 31 3338 1066

Email

abasazadbakht@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 2999

Email

hamidi_gh@kaums.ac.ir

Grant name

Vice chancellor for research, Kashan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Abbas Azadbakht

Position

Ph.D. student

Latest degree

Medical doctor

Other areas of specialty/work

Addiction Studies

Street address

No. 8187695895, East Shahidan

City

Isfahan

Province

Isfahan

Postal code

8187695895

Phone

+98 31 3338 1066

Fax
Email
azadbakht-a@mail.kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Abbas Azadbakht
Position
Ph.D. student
Latest degree
Medical doctor
Other areas of specialty/work
Addiction Studies
Street address
No. 8187695895, East Shahidan
City
Isfahan
Province
Isfahan
Postal code
8187695895
Phone
+98 31 3338 1066
Fax
Email
azadbakht-a@mail.kaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Abbas Azadbakht
Position
Ph.D. student
Latest degree
Medical doctor
Other areas of specialty/work
Addiction Studies
Street address

No. 8187695895, East Shahidan
City
Isfahan
Province
Isfahan
Postal code
8187695895
Phone
+98 31 3338 1066
Fax
Email
azadbakht-a@mail.kaums.ac.ir

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

For people working in academic institutions and businesses

Under which criteria data/document could be used

The documents will be shared for continuation and being executable of this study

From where data/document is obtainable

Email address

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

They will be received data until two weeks from them email.

Comments