

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of the effect of oxytocin on impulsivity and risky decision-making with regard to the oxytocin receptor gene (OXTR) among healthy young males

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of oxytocin on risky decision making and impulsivity among healthy young men according to the oxytocin receptor gene variants. The study population include male students aged 22 to 28 years from which, a sample of 120 people will be selected using convenience sampling and will be randomly assigned to test or control group. In pre-test phase, both groups will be evaluated by the Iowa gambling and go/ No-go tasks. Then, intervention group will receive 24 units oxytocin nasal spray and control group will receive 24 units placebo in a double-blind manner and only at once. After 45-60 minutes post-test will be done with aforementioned questionnaires. In addition, 5-10 ml of blood will be taken from each participant for DNA extraction and oxytocin receptor gene variants will be determined using RFLP method. Finally, scores of participants in the test and the control groups will be compared based on gene variants using two-way ANOVA. The main inclusion criteria include being placed in determined age range, filling out a consent form, no history of neurological and psychiatric problems and the lack of any drug and alcohol addiction. The main exclusion criterion is the lack of familiarity with the evaluation tests.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016051127842N1**

Registration date: **2016-08-12, 1395/05/22**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-08-12, 1395/05/22

##### Registrant information

###### Name

Ali Shahbazi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research and technology, Iran University of Medical Sciences

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-10-22, 1396/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of oxytocin on impulsivity and risky decision-making with regard to the oxytocin receptor gene (OXTR) among healthy young males

##### Public title

The effect of oxytocin hormone on impulsivity and risky decision-making with regard to the genetic variants

## Purpose

Basic science

## Inclusion/Exclusion criteria

Inclusion criteria: Perfect consciousness; being in the defined age range; Being a university student; Being male; Lack of mental disorder or neurological illness; Fill out the consent form. Exclusion criteria: being outside the defined age range; Being female; existence of mental disorders or neurological or hormonal problems or a history of them; Lack of adequate understanding of the process of project

## Age

From **18 years** old to **28 years** old

## Gender

Male

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **160**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Randomization will be done using sealed envelopes that puts people in the test or control group.

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway

##### City

Tehran

##### Postal code

#### Approval date

2016-06-21, 1395/04/01

#### Ethics committee reference number

IR.IUMS.REC 1395.9221559201

## Health conditions studied

### 1

#### Description of health condition studied

Impulsivity and decision making in healthy adults

#### ICD-10 code

-

#### ICD-10 code description

-

## Primary outcomes

### 1

#### Description

Impulsivity

#### Timepoint

Before the intervention, About 45-60 min after the intervention

#### Method of measurement

Go/No go task

### 2

#### Description

Risky decision making

#### Timepoint

Before intervention, About 45-60 min after the intervention

#### Method of measurement

IOWA Gambling task

### 3

#### Description

Oxytocin receptor gene variant

#### Timepoint

Before beginning the study

#### Method of measurement

PCR-RFLP Method

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Intervention group: healthy young men who will be selected based on inclusion criteria and will receive oxytocin nasal spray just once in a dose of 24 units. Oxytocin will be bought from Novartis Pharma and if the company cannot prepare the drug, the request will be sent to other companies.

**Category**

Treatment - Drugs

**2****Description**

Control group: This group includes healthy young men who will be selected based on inclusion criteria and will receive placebo just once.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Cellular and Molecular Lab, Department of Neuroscience, Iran University of Medical Sciences

**Full name of responsible person**

Ali Shahbazi

**Street address**

Department of Neuroscience, Faculty of advanced technologies in medicine, Iran University of Medical Sciences, Hemmat highway

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Iran University of Medical Sciences

**Full name of responsible person**

Ali Shahbazi

**Street address**

Shahid Hemmat highway

**City**

Tehran

**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 of Iran 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****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Ph.D. Deputy head of Neuroscience Department

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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*