Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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

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Ali Shahbazi
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Iran University of Medical Sciences
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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 scienece
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 dine 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 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
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Department of Neuroscience, Faculty of advanced technologies in medicine, Iran University of Medical Sciences, Hemmat highway
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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
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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
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
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Ali Shahbazi
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

Assistant Professor/PhD

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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