

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of oxytocin nasal spray with placebo on symptoms and treatment of adults with autism: a randomized clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of oxytocin nasal spray with placebo on symptoms and treatment of adults with autism

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase3,40 patients

Settings and conduct

Medications and tests are provided to patients in the Adult Developmental Disorders Clinic of Roozbeh hospital in Tehran by the administrator. The administrator and patients are not aware of which drug is placebo or main.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with autism; Age between 16 years and zero months to 55 years and 11 months; Confirmation of diagnosis by a psychiatrist based on DSM5; Complete physical examination and normal laboratory tests; Ability to read and understand the consent form in full and if it is not possible for the legal guardian to read and sign the form; Clinical global impression-severity CGI-S score above 4 in screening; Intelligence score in Stanford test - above 75. Exclusion criteria: Patients with nasal septal deformity and previous epithelial injuries and a history of nasal surgeries with a risk of nasal epithelium damage and people with a history of inhaled substance use; Patients with nasal congestion due to colds; Patients in the acute phase of psychiatric illness or with thoughts of death and suicide; Having a history of neurological diseases, seizures, and head injuries; Receive stimulant medications; People with a history of chronic oxytocin treatment; History of allergy to oxytocin and syntocin and all its compounds; asthma.

Intervention groups

The case group and the control group are patients with adult autism spectrum disorder. The case group will receive oxytocin nasal spray and the control group will

receive placebo nasal spray.

Main outcome variables

Improve social interactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046938N1**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Saba Faraji niri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2282 9356

Email address

s_farajin@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of oxytocin nasal spray with placebo on symptoms and treatment of adults with autism: a randomized clinical trial

Public title

Evaluation of the effectiveness of oxytocin by placebo nasal spray on symptoms and treatment of adults with autism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 16 years and zero months to 55 years and 11 months Confirmation of diagnosis by a psychiatrist based on dsm5 Complete physical examination and normal laboratory tests Ability to understand and speak Persian fluently Ability to read and understand the consent form in full and if it is not possible for the legal guardian to read and sign the form Clinical global impression-severity CGI-S score above 4 in screening Intelligence score in Stanford test - above 75

Exclusion criteria:

Patients with nasal septal deformity and previous epithelial injuries and a history of nasal surgeries with a risk of nasal epithelium damage and people with a history of inhaled substance use Patients with nasal congestion due to colds Patients in the acute phase of psychiatric illness or with thoughts of death and suicide Having a history of neurological diseases, seizures and head injuries People with a history of neurological or metabolic disease that affects their sensory and motor function, etc. Receive stimulant medications History of uncontrolled cardiovascular, renal and hepatic diseases Pregnant women or young women who do not take oral contraceptives People whose type and dose of psychiatric medication have changed in the last 4 weeks People with a history of chronic oxytocin treatment History of allergy to oxytocin and syntocin and all its compounds asthma

Age

From **16 years** old to **56 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was performed. It was an individual randomization unit. Forty adult patients with autism spectrum disorder are numbered from 1 to 40 in the Excel file. Then in Random Allocation software, the number of patients was 40. The number of groups was set at 2. Group 1 case name and group 2 placebo name were determined. Then the software determined which number is in the case group and which number is in the placebo group. The numbers were matched with an Excel file containing the patients' names, thus identifying the case and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and their companions and the prescribing physician will be unaware of which is the main drug and which is the placebo. There will be only codes on the bottles that will be registered with the name of the person when prescribing to the patient.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran university of medical sciences, school of medicine, porsina street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.096

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

Autistic Disorder

ICD-10 code

F84.0

ICD-10 code description

Primary outcomes

1

Description

Improving the social symptoms of adults with autism

Timepoint

Start of study, 4 weeks later, 8 weeks later

Method of measurement

Social responsiveness scale -social motivation subscale (SRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oxytocin nasal spray, including oxytocin peptide, 25 ml bottle, 2 times a day, two puffs in each nostril, including 48 international units of oxytocin daily, for 8 weeks, Pharma Globe (Pharma Grid) UK.

Category

Treatment - Drugs

2

Description

Control group: normal saline nasal spray, 25 ml, twice a day, two puffs per nose, for 8 weeks, Jaber Ibn Hayyan Co.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr Javad Alaghbandrad

Street address

Roozbeh Hospital,south Kargar Street,Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Sahraeean

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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

Saba Faraji Niri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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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