Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 syntocinin 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 syntocinin 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,poursina 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

Autistic disorder

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
City
Tehran
Province
Tehran
Postal code
13337159140
Phone
+98 21 5541 9151
Email
saba_faraji@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Sahraeean
Street address
Tehran University of Medical Sciences, Poor Sina Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8891 2091
Email
tumspr@tums.ac.ir
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
Street address
No 151,razi tower,saboori ave,kashanak ave,niavaran square,tehran
City
Tehran
Province
Tehran
Postal code
1978976181

Phone
+98 21 2282 9356
Fax
Email
S_farajin@razi.tums.ac.ir

Person responsible for scientific 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
Street address
No 151,razi tower,saboori ave,kashanak ave,niavaran square,tehran
City
Tehran
Province
Tehran
Postal code
1978976181
Phone
+98 21 2282 9356
Fax
Email
S_farajin@razi.tums.ac.ir

Person responsible for updating data

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
Street address
No 151,razi tower,saboori ave,kashanak ave,niavaran square,tehran
City
Tehran
Province
Tehran
Postal code
1978976181
Phone
+98 21 2282 9356
Fax
Email
S_farajin@razi.tums.ac.ir

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