

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The efficacy of intranasal oxytocin before applied behavior analysis (ABA) therapy of youth (4-17 years old) with autistic spectrum disorder

Protocol summary

2021-12-28, 1400/10/07

Study aim

The efficacy of intranasal oxytocin before applied behavior analysis (ABA) therapy of youth (4-17 years old) with autistic spectrum disorder

Design

randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 70 patients

Settings and conduct

In this randomized double-blind clinical trial study, 70 autism patients referred to Isfahan Khorshid Hospital will be included in the study and randomly divided into 2 groups. One group will receive oxytocin and the other group will receive normal saline. Then the severity of autism and the strength and difficulties of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

having autism disorder and not having endocrine disease and head trauma and neurologic problem

Intervention groups

Autism patients are divided into two groups. Oxytocin spray will be prescribed for patients in the intervention group and normal saline spray will be prescribed for patients in the control group.

Main outcome variables

The severity of autism; The strength and difficulties

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052670N1**

Registration date: **2021-12-28, 1400/10/07**

Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**

Update count: **0**

Registration date

Registrant information

Name

afsaneh karbasi amel

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3641 1255

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of intranasal oxytocin before applied behavior analysis (ABA) therapy of youth (4-17 years old) with autistic spectrum disorder

Public title

The efficacy of intranasal oxytocin before applied behavior analysis (ABA) therapy with autistic spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

autism 4-17 year old

Exclusion criteria:
endocrine disease head thruma neurologic problem

Age
From **4 years** old to **17 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The method is permuted block randomization. In this way, first using online software (sealed envelope), a sequence of random numbers will be created and by the same software, the generated numbers will be divided into 7 blocks of 10. Which is an equal number in each block will be 5 items from the intervention group and 5 items from the control group. So by doing each block, 5 patients (equally) will be assigned to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Before starting the study, the spray containing oxytocin and normal saline is prepared by the pharmacist in similar containers, with the same color and smell, and is labeled with codes A and B and given to the researcher. And they prescribe them without knowing the type of each drug. Also, the Patient, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Street address Esfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Esfahan

Province
Isfahan

Postal code
8179964167

Approval date
2021-09-04, 1400/06/13

Ethics committee reference number
IR.MUI.MED.REC.1400.442

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Severity of autism

Timepoint

Before the intervention, the sixth week during the intervention and 6 weeks after the intervention

Method of measurement

Gilliam Autism Rating Scale (GARS)

2

Description

Strenght and Difficulties

Timepoint

Before the intervention, the sixth week during the intervention and 6 weeks after the intervention

Method of measurement

Strengths and Difficulties Questionnaire (SDQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients have been prescribed three puffs of oxytocin spray in each nostril (4 IU per puff). Before the spray and half an hour after the end of the spray, vital signs include body temperature, blood pressure, and heart rate. Patients will then undergo Applied Behavior Analysis (ABA) therapy intervention. Patients will be sprayed with ABA at intervals of one week and continuously for six weeks.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients have been prescribed three puffs of normal saline spray in each nostril (4 IU per puff). Before the spray and half an hour after the end of the spray, vital signs include body temperature, blood pressure, and heart rate. Patients will then undergo Applied Behavior Analysis (ABA) therapy intervention. Patients will be sprayed with ABA at intervals of one week and continuously for six weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Safie shafiezhadegan Esfahani

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Second Apadana Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Vice Chancellor for Research, School of Medicine,
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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Safie Shafiezhadegan-Isfahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available