

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of intranasal oxytocin on negative symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of intranasal oxytocin would improve psychopathology in subjects with schizophrenia treated with Risperidone. 50 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=20) or daily intranasal oxytocin (titrated to 40 IU twice a day, N=20) for 8 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Positive and Negative Syndrome Scale (PANSS). Side effects will be also evaluated using checklist and Extra-pyramidal Symptoms Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202251556N35**

Registration date: **2012-02-27, 1390/12/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,,Tehran University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-08-31, 1391/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intranasal oxytocin on negative symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Public title

intranasal oxytocin in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-50, Diagnosis of Schizophrenia based on DSM IV 3 chronic Schizophrenia(duration of the disorder>2 years), Minimum Score of 60 on Positive and Negative Scale- Exclusion Criteria:1- Substance dependence,2- IQ <70, 3-any other mental disorder on axis I, 4-Any serious medical or neurological problem ,5- receiving ECT during the last 14 days, 6- hepatic disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

12949

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

schizophrenia

Primary outcomes

1

Description

Severity of schizophrenia

Timepoint

Baseline and weeks 2-4-6-8 after beginig of treatment

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description

Risperidone combined with placebo for 8 weeks

Category

Placebo

2

Description

Risperidone combined with intranasal oxytocin(titrated to 40IU /twice day) as intervention group for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshvarz Blvd

City

Tehran

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

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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Person responsible for updating data

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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