Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Sublingual Atropine on Sialorrhea Induced by Clozapine in Patients with Schizophrenia

Protocol summary

Study aim
Effect of sublingual atropine on sialorrhea induced by Clozapine in patients with schizophrenia

Design
A clinical trial with a control group, parallel groups, double-blind, randomized, phase 3 per 62 patients. Computer-generated random numbers will be used for randomization.

Settings and conduct
This study was designed to investigate the effect of sublingual atropine administration on sialorrhea caused by clozapine in patients with schizophrenia who referred to Qods Hospital in Sanandaj. After dividing the patients into two intervention and control groups two drops of atropine sulfate 1% It will be administered under the tongue in the intervention group or placebo in the control group. In order to blind the study, the patients, the physician and the evaluator of the patients are not aware of the grouping of the studied patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years; Diagnosed schizophrenia; Current use of Clozapine for treatment; Presence of drooling. Exclusion criteria: Pregnancy and breastfeeding; Cardiovascular problems (arrhythmia, blood pressure, etc.); History of taking other anticholinergics.

Intervention groups
After washing and cleaning the mouth, two drops of atropine sulfate 1% in the intervention group or placebo in the control group will be administered under the tongue, for 4 weeks and every night 1 hour before going to sleep.

Main outcome variables
sialorrhea (drooling)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221101056373N1**
Registration date: **2022-11-12, 1401/08/21**
Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**
Update count: **0**

Registration date
2022-11-12, 1401/08/21

Registrant information

Name
Sima Sardari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3366 0025

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sima_sardari83@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Sublingual Atropine on Sialorrhea Induced by Clozapine in Patients with Schizophrenia

Public title

Effect of Sublingual Atropine on Sialorrhea Induced by Clozapine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Diagnosed schizophrenia Current use of Clozapine for treatment Presence of drooling

Exclusion criteria:

Pregnancy and breastfeeding Cardiovascular problems (arrhythmia, blood pressure, etc.) History of taking other anticholinergics

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done randomly using computer generated random numbers. Thus, each "odd number" produced belongs to group 1 (intervention group) and each randomly generated "even number" belongs to group 2 (patient placement in the control group)

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, patients and their families do not know which of the intervention or control groups they are in. Also, the medicine and placebo are prepared in similar containers and in the same quantity, appearance and taste, and after coding by a psychiatric assistant, who does not know about the grouping, the drugs are prescribed. The final evaluation and summarization of the patients' findings will also be done by a psychiatric assistant who is not part of the group of study patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd

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Sanandaj

Province

Kurdistan

Postal code

6617913446

Approval date

2022-09-21, 1401/06/30

Ethics committee reference number

IR.MUK.REC.1401.226

Health conditions studied

1

Description of health condition studied

Clozapin induced sialorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sialorrhea

Timepoint

For 4 weeks and every night 1 hour before sleep

Method of measurement

Visual analogue scale and Drooling Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After washing and cleaning the mouth, for 4 weeks and every night 1% hour before sleeping, two drops of atropine sulfate will be administered under the tongue.

Category

Treatment - Drugs

2

Description

Control group: After washing and cleaning the mouth, for 4 weeks and every night 1 hour before sleeping, two drops of placebo will be administered under the tongue.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Qods Hospital
Full name of responsible person
Sima Sardari
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Sponsors / Funding sources

1

Sponsor

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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
Sanandaj 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
Sanandaj University of Medical Sciences
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Position
Associate professor
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable