Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of effects of atropine drops and Amitriptyline tablets in clozapine-induced hypersalivation

Protocol summary

Summary

The object of this randomized, placebo controlled, double blind study is Comparison of effect of atropine drops and Amitriptyline tablet in clozapine-induced hypersalivation in psychotic patients. 40 patients with ages between 18-65 years who have no other medical conditions, with DSMIV-TR diagnosed Schizophrenia and other psychotic disorders will receive Amitryptiline tablet and Placebo drop(n=20) and other group will receive Atropine drop and Placebo tablet for 4 weeks.The amount of sialorrhea in patient will measure daily in first week and then weekly until 4 weeks based on TNHS and Drooling scale.Side effects will be evaluated at baseline and then weekly with CGI scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701136691N3**
Registration date: **2017-02-15, 1395/11/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-15, 1395/11/27

Registrant information

Name

Fatemeh Sheikhmoonesi

Name of organization / entity

Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of atropine drops and Amitriptyline tablets in clozapine-induced hypersalivation

Public title

Comparison of effect of atropine drops and Amitriptyline tablet in clozapine-induced hypersalivation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Every hospitalized patient taking Clozapine and recieved diagnosis of Schizophrenia, Schizoaffective or other psychiatric disorders according to DSM-IV ; Age between 18-65 year old ; Having nacturnal sialorrhea more than 2 scores based on TNHS ; Agreement and optional participation of patients is necessary. Exclusion criteria: Sensitivity to Atropine and Amitriptyline ; Comorbidity with other diseases produce sialorrhea like Parkinson dx and Cerebral palsy ;Affliction with untreated constipation, Bladder outlet obsrtuction and urinary retention; Co-consumption of anticholinergic drugs ; Lactation &Pregnancy ; past positive history of myasthenia gravis, Cardiac arrythmia, Glucoma, Pyloric obsrtruction,Paralytic ileus, Prostatic hypertrophia and

Renal dysfunction ; Sever dysoutonomy 8. Mental retardation 9. Bipolar schizoaffective and Bipolar mood disorder

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
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
Mazandaran University of Medical Sciences

Street address
Central building of Mazandaran University of Medical Scienses and Health Service, Daneshgah Blvd, Emam Square

City
sari

Postal code
48154

Approval date
2016-11-26, 1395/09/06

Ethics committee reference number
IR.MAZUMS.REC.95.1747

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Severity and Frequency of sialorhea

Timepoint
Daily in first week and then weekly until4 weeks

Method of measurement
Toronto Nacturnal Hypersalivation Scale,Drooling scale

Secondary outcomes

1

Description
Palpitation

Timepoint
Baseline and weeks 1-2-3-4 after begining of treatment

Method of measurement
puise rate measuring at Baseline and weeks 1-2-3-4 after begining of treatment

2

Description
Hypertension

Timepoint
Baseline and weeks 1-2-3-4 after begining of treatment

Method of measurement
Blood pressure measuring at Baseline and weeks 1-2-3-4 after begining of treatment

Intervention groups

1

Description
Within 4 weeks 1 group of patient will recieve Amytriptiline tablet and Placebo drop .

Category
Treatment - Drugs

2

Description
within 4 weeks other group will recieve Atropine drop and placebo tablet.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Fatemeh Sheikhmoonesi

Street address
Zare Psychiatry Hospital

City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmadali Enayati
Street address
Vice Chancellor for Research and Technology, Building N.2, Moallem Square, Moallem Street
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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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Dr Fatemeh Sheikhmoonesi
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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