Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Randomized clinical trial of the effect of oxybutinine on serteralin induced sweating in patients with depression

Protocol summary

Summary

Sweating is common side effect in patients who use sertraline. This study will be conducted to evaluate the effect of oxybutinine on serteralin induced sweating in patients with depression. In this double blind clinical trial, according to diagnostic and statistical manual IV-TR criteria, patients with diagnosis of major depressive disorder and are under treatment with serteraline and having sweating, will be randomly assign in two groups(intervention group and control group). After signing the informed consent, the degree of the patients' sweating will be recorded. Intervention group will take 5 mg of oxibutinine twice a day and control group will take placebo twice a day for two weeks. After 2weeks, patients sweating degree will be re-evaluated. Then the results will be compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101045547N1**
Registration date: **2011-05-16, 1390/02/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-16, 1390/02/26

Registrant information

Name

Zahra Sherafat

Name of organization / entity

Medical sience university

Country

Iran (Islamic Republic of)

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+98 913 357 0273

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Hamedan Univerity of Medical Sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of the effect of oxybutinine on serteralin induced sweating in patients with depression

Public title

Effect of oxybutinine on serteralin induced sweating in patients with depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major depressive disorder according to diagnostic and statistical manual IV- TR criteria that are using serteraline as a treatment and have sweating as side effect Exclusion criteria: Patients with psychotic features; addiction; anxiety disorders; age under18 and above65 years old; patients with hypertension, cardiac disease, urinary problems, cataract, increased eye pressure; patient with personality disorder and patients who are taking the other medications

Age

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Medical sience university of hamedan

Street address
Medical sience university of hamedan

City
Hamedan

Postal code

Approval date
2010-12-06, 1389/09/15

Ethics committee reference number
137614/9/35/16پ

Health conditions studied

1

Description of health condition studied
Mjor depressive disorder

ICD-10 code
F32.9

ICD-10 code description
Depressive episode, unspecified

Primary outcomes

1

Description
Sweating

Timepoint
Before intervention, 2weeks after intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
]Intervention group: oxybutinine tablet 5mg 2 times a day for 2 weeks

Category
Treatment - Drugs

2

Description
Control group: Placebo tablets, two times a day or 2 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Farshchian psychiatry hospital

Full name of responsible person
Dr.Sherafat.zahra

Street address
Clinic of Farshchian psychiatry hospital

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Medical sience university of hamedan

Full name of responsible person
Dr.Ghaleiiha.Ali

Street address
Deputy of research,Medical sience university of hamedan

City
Hamedan

Grant name

Grant code / Reference number

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

Title of funding source
Medical sience university of hamedan

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.Sherafat.zahra
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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