

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Scopolamine as adjuvant therapy in the treatment of major depression: a randomised and double blind study

#### Protocol summary

##### Summary

The purpose of the present investigation is to assess the efficacy of scopolamine as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 40 adult outpatients who meet the DSM- IV-TR criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 22 will be allocated into two groups. 20 patients will receive Citalopram 40 mg/day plus Scoploamine 10 mg/day and 20 participants will receive Citalopram 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after day 4, 7, 14, 28 and 42. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201181556N31**

Registration date: **2012-01-19, 1390/10/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-19, 1390/10/29

##### 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

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2011-11-10, 1390/08/19

##### Expected recruitment end date

2012-04-10, 1391/01/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Scopolamine as adjuvant therapy in the treatment of major depression: a randomised and double blind study

##### Public title

Scoploamine in the treatment of major depression

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Presence of Major Depressive Disorder based on DSM-IV criteria; Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 22.

Exclusion criteria: Presence of Psychosis, any other diagnosis in Axis I and II; Receiving psychotropic medications; receiving any antidepressants during past one month or ECT during past two months; Presence of hypothyroidism or cardiovascular problems and pregnancy or nursing women

##### Age

From **18 years** old to **55 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

Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2011-04-21, 1390/02/01

#### Ethics committee reference number

10349

## Health conditions studied

### 1

#### Description of health condition studied

Major Depressive episode

#### ICD-10 code

F-32

#### ICD-10 code description

Major Depressive episode

## Primary outcomes

### 1

#### Description

Severity of depression

#### Timepoint

Baseline and day 4, 7, 14, 28, and 42

#### Method of measurement

Hamilton Depression Rating Scale 17-Item

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Tablet Citalopram 40 mg/day plus Tablet Scoplamine 10 mg/day as intervention group for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Tablet Citalopram 40 mg/day plus Tablet placebo as control group for 6 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh Hospital

##### Full name of responsible person

Prof. shahin Akhondzadeh

##### Street address

Roozbeh Hospital -south Kargar street

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Fotouhi

##### Street address

Keshavarz 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. shahin Akhondzadeh

**Position**

PhD of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Hospital - South Kargar street

**City**

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**Email**

s.akhond@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

PhD of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Hospital - South Kargar street

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**Web page address****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*