

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The augmentation effect of injectable scopolamine in the improvement of clinical symptoms of patients with major depressive disorder

#### Protocol summary

##### Study aim

The augmentation effect of injectable scopolamine in the improvement of clinical symptoms of patients with major depressive disorder

##### Design

The current clinical trial study has a control group, with parallel groups, without blinding, randomized (using block randomization), phase 3 on 46 patients.

##### Settings and conduct

In this randomization clinical trial, patients with major depressive disorder with minimum severity of Hamilton depression scale 20 referred to Amirkabir Arak hospital were divided into two equal groups of standard treatment and scopolamine treatment by means of block randomization. In the standard treatment group, patients will receive standard treatment and in the scopolamine group, patients will receive 0.5 mg of scopolamine intramuscularly daily for three days. Finally, two groups will be evaluated in terms of the desired outcome.

##### Participants/Inclusion and exclusion criteria

Eligibility conditions: patients with major depressive disorder; age 55-18 years; Minimum severity of depression based on Hamilton Depression Scale should be higher or equal to 20. Conditions for not entering the study: presence of psychotic disorder; delirium and bipolar, pregnancy or breastfeeding; taking psychedelic drugs, antidepressants in the last month; ECT in the last two months; history of cardiovascular disease; Hypothyroidism

##### Intervention groups

In the standard treatment group, patients will receive the standard treatment of major depressive disorder. In the scopolamine treatment group, in addition to the standard treatment of major depressive disorder, patients will receive 0.5 mg of scopolamine intramuscularly daily for three days.

##### Main outcome variables

Hamilton depression scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231017059749N1**

Registration date: **2023-10-21, 1402/07/29**

Registration timing: **prospective**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

##### Registration date

2023-10-21, 1402/07/29

##### Registrant information

##### Name

Amin Hoseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3369 1709

##### Email address

drhoseini.amin@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-22, 1402/07/30

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The augmentation effect of injectable scopolamine in the improvement of clinical symptoms of patients with major depressive disorder

**Public title**

The effect of injectable scopolamine in patients with major depressive disorders

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with major depressive disorder Age 18-55 years  
Minimum severity of depression based on Hamilton Depression Scale should be higher or equal to 20.

**Exclusion criteria:**

The existence of psychotic disorder, delirium and bipolar disorder  
Pregnancy or breastfeeding  
Taking psychedelic drugs, antidepressants in the last month  
ECT in the last two months  
History of cardiovascular disease  
Hypothyroidism

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, randomized block method will be used for randomization into two groups of scopolamine (group A) and treatment with standard treatment (group B). For this purpose, a block of 4 will be used. Four cards are selected, the letter A is written on two cards, and the letter B is written on the other two cards. In order to hide the cards, they are placed inside the envelope and turned over several times so that the order is not clear. When each participant enters, a card is selected for him and the selected card is discarded; This work is also done for the next patient to determine 4 people. Then, in the same way, randomization will be done for other groups of 4 people to reach the desired sample size.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

**Street address**

Vice chancellor for research, Arak University of Medical Sciences, Basij Square, Arak, Iran

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2022-08-28, 1401/06/06

**Ethics committee reference number**

IR.ARAKMU.REC.1401.168

**Health conditions studied****1****Description of health condition studied**

Major depressive disorder

**ICD-10 code**

F32

**ICD-10 code description**

Major depressive disorder, single episode

**Primary outcomes****1****Description**

Hamilton depression scale

**Timepoint**

The beginning of the study, the fourth day, the seventh day, the fourteenth day, the twenty-eighth day

**Method of measurement**

Hamilton questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In addition to standard treatment (SSRI), patients will receive 0.5 mg scopolamine intramuscularly daily for three days.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Patients will receive standard

treatment (SSRI).

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Arak Amir Kabir Hospital

**Full name of responsible person**

Dr. Anita Alaghmand

**Street address**

Vice Chancellor for Education, Amir Kabir Hospital,  
Arak, Iran

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Salehi

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Research Assistant, Arak University of Medical  
Sciences, Basij Square, Sardasht, Arak, Iran

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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**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kmali

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Sabouri

**Position**

resident

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Specialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

**When the data will become available and for how long**

Access will be from 2024/01/20 to 2027/01/20 for 3 years.

**To whom data/document is available**

University researchers

**Under which criteria data/document could be used**

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

**From where data/document is obtainable**

Academic researchers and university professors can request the use of data from Dr. Ali Sabouri after contacting the relevant official via message or email. Dr. Ali Sabouri: Phone: 09126031453 Email: ali.sabouri1987@gmail.com Address: Arak, Amirkabir Hospital, Hospital Education Vice-Chancellor

**What processes are involved for a request to access data/document**

Letter writing should be done with professors and universities.

**Comments**