Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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
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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 disorderPregnancy 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
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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
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Sponsors / Funding sources

1

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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
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Associate Professor

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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