

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of Ketamine and Propofol and Dexmedetomidine in treatment with electroconvulsive therapy in patients with resistant to treatment major depressive disorder

Protocol summary

Study aim

Comparison of the effects of Ketamine and Propofol and Dexmedetomidine in treatment with electroconvulsive therapy in patients with resistant to treatment major depressive disorder

Design

This double-blind and clinical trial .68 Patient candidate with resistant major depression requires electroshock in psychiatric department of Amirkabir Hospital of Arak. We will divide patients in 4 groups by simple randomization. Groups are parallel.

Settings and conduct

This double-blind and clinical trial .68 Patient candidate with resistant major depression requires electroshock in the psychic section in Amirkabir Hospital of Arak. We will divide patients in 4 groups by simple randomization. The study is double-blind. Outcome evaluator and analyzer and participant are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 60 years, both sexes, patients with a diagnosis of schizophrenia Exclusion criteria: no history of drug use, no pregnancy, no history of cardiovascular disease, do not take beta-blockers, lack of sensitivity to the drugs used in this study, there are no contraindications to ECT, such as spinal cord injury and high ICP, and recent heart attacks

Intervention groups

Intervention group: We inject 0.2 micro grams per kilogram Dexmedetomidine in 10 millilitre normal saline for 10 minute slowly. Intervention group: We inject 1/5 milligram per kilogram Propofol in 10 millilitre normal saline for 10 minute slowly. Intervention group: We inject 0/8 milligram per kilogram Ketamin in 10 millilitre normal saline for 10 minute. Control group: We inject 10 millilitre normal saline as placebo for 10 minute.

Main outcome variables

Seizure duration, patient satisfaction, recovery duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N143**

Registration date: **2020-06-21, 1399/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-21, 1399/04/01**

Update count: **0**

Registration date

2020-06-21, 1399/04/01

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the effects of Ketamine and Propofol and Dexmedetomidine in treatment with electroconvulsive therapy in patients with resistant to treatment major depressive disorder
Public title	Comparison of the effects of Ketamine and Propofol and Dexmedetomidine in treatment with electroconvulsive therapy in patients with depression
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	18 to 60 years Both sexes Patients with a diagnosis of schizophrenia
Exclusion criteria:	No history of drug use No pregnancy No history of cardiovascular disease (arrhythmias, ischemia, heart block) Do not take beta-blockers There are no contraindications to ECT, such as spinal cord injury and high ICP, and recent heart attacks.
Age	From 18 years old to 60 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Outcome assessor • Data analyser
Sample size	Target sample size: 68
Randomization (investigator's opinion)	Randomized
Randomization description	Simple individual randomization with randomization with envelopes in 4 groups A and B and C and D . In this method, we write a few cards or letters as intervention groups and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the other cards after leaving. Then the cards are mixed again and then another card is picked up. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)	Double blinded
Blinding description	This study is clinical trial.Outcome evaluator and analyzer and participant are blind (double blind).Outcome evaluator and analyzer and participant don't aware from grouping.
Placebo	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	Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak
City	Arak
Province	Markazi
Postal code	3848176941
Approval date	2020-01-18, 1398/10/28
Ethics committee reference number	IR.ARAKMU.REC.1398.290
Health conditions studied	
1	
Description of health condition studied	Schizophrenia
ICD-10 code	F20
ICD-10 code description	Schizophrenia
Primary outcomes	
1	
Description	Heart rate
Timepoint	Every 5 minutes
Method of measurement	Counting
2	
Description	Mean blood pressure
Timepoint	Every 5 minutes
Method of measurement	Barometer
3	
Description	Seizure duration
Timepoint	In times of seizures

Method of measurement

Minutes

4**Description**

Patient satisfaction

Timepoint

After the shock

Method of measurement

Satisfaction Questionnaire

5**Description**

Recovery duration

Timepoint

After the shock

Method of measurement

Minute

Secondary outcomes

empty

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

Intervention group 1: We inject 0.2 micro grams per kilogram Dexmedetomidine (Prizer-America) in 10 millilitre normal saline for 10 minute slowly.

Category

Treatment - Drugs

2**Description**

Intervention group 2: We inject 1.5 milligram per kilogram Propofol(Tehran shimi-Iran) in 10 millilitre normal saline for 10 minute slowly.

Category

Treatment - Drugs

3**Description**

Intervention group 3: We inject 0.8 milligram per kilogram Ketamin (ROTEXMEDICA -Germany) in 10 millilitre normal saline for 10 minute.

Category

Treatment - Drugs

4**Description**

Control group: We inject 10 millilitre normal saline as placebo for 10 minute.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amirkabir hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Amirkabir hospital, Parastar square, Arak

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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 Behnam Mahmodie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Arak University of Medical Sciences

Full name of responsible person

Aida Abdos

Position

Medicine student

Latest degree

Medical doctor

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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Hesamodin Modir

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

They have to write letters to the professors and the university.

Comments