Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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 elevator 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 elevator and analyzer and participant are blind (double blind).Outcome elevator 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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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
Street address
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

Street address

Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

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

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Aida Abdos

Position

Medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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