

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison the effect of adjuvant Remifentanyl, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

Protocol summary

Study aim

Comparison the effect of adjuvant Remifentanyl, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

Design

The study will be double blind and clinical trial. 90 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

patients with major depressive disorder candidates for electroconvulsive therapy in Amirkabir Hospital in Arak are divided into 3 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with major depressive disorder are candidates for ECT, consent to participate in the study, 18 to 60 years, body mass index 20 to 30, no history of underlying heart, lung, kidney and liver diseases, no history of recent CVA or MI, insensitivity to drugs. Exclusion criteria: all patients who experience cardiorespiratory arrest during ECT, all patients who need intubation after ECT due to prolonged apnea and respiratory failure, all patients who do not experience sufficient and desired seizures during ECT, all patients who want to withdraw from the study or do not want to continue electroshock therapy

Intervention groups

Intervention group 1: Before induction of anesthesia, 100 micrograms of Remifentanyl is injected intravenously. Intervention group 2: Before the induction of anesthesia, intravenous injection of 0.5 mg/kg Dexmedetomidine is performed. Intervention group 3: After induction of anesthesia as mentioned above, immediately before stimulation with ECT, an amount of 2.5 mg Metoral is

injected.

Main outcome variables

Average blood pressure, average heart rate, average percentage of oxygen saturation, patient satisfaction, agitation, seizure duration, recovery period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N178**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **prospective**

Last update: **2022-12-31, 1401/10/10**

Update count: **0**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision the effect of adjuvant Remifentanil, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

Public title
Comparision the effect of adjuvant Remifentanil, Dexmedetomidine or metoral with thiopental on hemodynamic status in patients with major depressive disorder candidates for electroconvulsive therapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with major depressive disorder are candidates for ETC Consent to participate in the study 18 to 60 years Body mass index 20 to 30 Patients with major depressive disorder who do not have other psychiatric illnesses at the same time. No history of underlying heart, lung, kidney and liver diseases No history of recent CVA or MI Insensitivity to Remifentanil or Dex Medtomidine or Metoral or Thiopental All patients who are indicated to receive ECT according to psychiatric treatment criteria. Absence of pregnancy and breastfeeding
Exclusion criteria:
All patients who experience cardiorespiratory arrest during ECT. All patients who need intubation after ECT due to prolonged apnea and respiratory failure All patients who do not experience sufficient and desired seizures during ECT. All patients who want to withdraw from the study or do not want to continue electroshock therapy.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 3 and 6. Random sequence will be generated by an epidemiologist by running an online program in

sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is carried out in such a way that after obtaining the informed consent of the patients to participate in the study, using the randomized block method, the patients are completely randomly assigned to three equal groups of remifentanil and thiopental (group A) and dexmedomidine by the anesthesiologist. and thiopental (group B) and Metoral and thiopental (group C) are divided. Then, the drugs are prepared in advance by the anesthesiologist in charge of the plan and given to the fellow anesthesia resident who does not know the type of drugs. In all three drug groups that are used for the intervention (remifentanil-thiopental, dexmedomidine-thiopental, and metoral-thiopental), the syringes are of the same shape, and the volume of the injected drug is adjusted to CC5 in order to comply with the blinding. Also, the intern in charge of the project did not know the type of study groups from the beginning, and only after ECT induction for the patients, he is responsible for filling the questionnaires of the project, and therefore, he is not aware of the type of study groups.

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
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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Arak
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Postal code
848176941

Approval date
2022-10-09, 1401/07/17

Ethics committee reference number
IR.ARAKMU.REC.1401.206

Health conditions studied

1

Description of health condition studied

major depressive disorder candidates for electroconvulsive therapy

ICD-10 code

F06.32

ICD-10 code description

Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

Average blood pressure

Timepoint

Recovery

Method of measurement

Barometer

2

Description

Average heart rate

Timepoint

Recovery

Method of measurement

Pulse oximeter

3

Description

Average percentage of oxygen saturation,

Timepoint

Recovery

Method of measurement

Pulse oximeter

4

Description

Patient satisfaction

Timepoint

Recovery

Method of measurement

Question

5

Description

Agitation

Timepoint

Recovery

Method of measurement

Physical examination

6

Description

Seizure duration

Timepoint

Recovery

Method of measurement

Observation

7

Description

Recovery period

Timepoint

Recovery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Before induction of anesthesia, 100 micrograms of remifentanyl is injected intravenously

Category

Treatment - Drugs

2

Description

Intervention group 2: Before the induction of anesthesia, intravenous injection of 0.5 mg/kg dex methomidine is performed.

Category

Treatment - Drugs

3

Description

Intervention group 3: After induction of anesthesia as mentioned above, immediately before stimulation with ECT, an amount of 2.5 mg Metoral is injected .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr HALireza Kamali

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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

Arak University of Medical Sciences

Full name of responsible person

Dr Anita Alaghemand

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available