Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Study aim

Comparision the effect of adjuvant Reminfentanil, 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 ETC ,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 group1: Before induction of anesthesia, 100 micrograms of Remifentanil is injected intravenously. Intervention group 2: Before the induction of anesthesia, intravenous injection of 0.5 mg/kg Dexmethomidine 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

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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 Reminfentanil, 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 Reminfentanil, 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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Markazi

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 remifentanil 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

Sponsor

Name of organization / entity
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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

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Psychiatrics

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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