Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the Effect of Remifentanil-Thiopental and Ketofol on Homodynamic Responses in Patients with Major depressive disorder candidates for Electro Convulsive Therapy

Protocol summary

Study aim

Determining the effect of Remifentanil and Thiopental (group A) and Ketofol (group B) on hemodynamic status, agitation and satisfaction of patients with major depression who are candidates for electroconvulsive therapy

Design

Double-blind clinical trial, with parallel groups, phase 3, on 80 patients, randomly divided into two groups using block random method

Settings and conduct

This study is a double-blind clinical trial. 80 patients with major depressive disorder who are candidates for electroconvulsive therapy referred to Amir Kabir Hospital in Arak are included in the study. They are divided into two groups using block random method. And since this study will be conducted in double-blind method, in addition to patients, the anesthesia resident who is the assistant of the project and the intern in charge of the project will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 60 years; with major depression Candidate for ECT; BMI in the range of 20 to 30 . Exclusion criteria: history of underlying diseases; pregnancy; lactation

Intervention groups

Intervention group: In group B, the anesthesia process is induced by intravenous injection of 0.5 mg / kg ketamine with 0.5 mg / kg propofol (ketofol). Control group: In group A, 100 micrograms of remifentanil is injected intravenously before induction of anesthesia, then the anesthesia process is induced by injection of 2-3 mg / kg thiopental.

Main outcome variables

Mean arterial pressure; heart rate; blood oxygen saturation level; Satisfaction score; agitation score; seizure duration; recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051672N1**
Registration date: **2021-07-22, 1400/04/31**
Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**
Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Parisa Tavakoli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the Effect of Remifentanil-Thiopental and Ketofol on Homodynamic Responses in Patients with Major depressive disorder candidates for Electro Convulsive Therapy

Public title
Comparison the Effect of Remifentanil-Thiopental and Ketofol in major depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with major depressive disorder candidates for Electro Convulsive Therapy referred to Arak Amirkabir Hospital All patients candidates for Electro-Convulsive Therapy who have signed an informed consent form to enter the study Patients in the age range of 18 to 60 years Patients with a BMI in the range of 20 to 30 Patients with major depressive disorder who do not have another psychiatric illness at the same time

Exclusion criteria:
Pregnancy Breastfeeding sensitivity to Remifentanil or Thiopental or Propofol taking anticonvulsant drugs recent CVA or MI history history of underlying diseases of the heart, lungs, kidneys and liver

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients with inclusion criteria are randomly divided into two equal groups of remifentanil and thiopental (group A) and ketofol (group B) by the Anesthesia technician of the project. In this method, we have a total of 8 blocks that are formed based on the variables; The size of each block is 10 people and within each block, half of the patients from the intervention group and half from the control group are included.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs are prepared by an anesthesiologist in charge of the project and given to a fellow anesthesia resident who does not know the type of drugs. In both groups, the drug used for the intervention (remifentanil-thiopental and ketofol) is in the similar syringes and the volume of the injectable drug is increased to 5 cc for blinding. Then, the information obtained from patients will be recorded in the form of a project questionnaire by the intern in charge of the project. Finally, the information obtained from the questionnaire will be analyzed by SPSS 21 software using statistical tests and will be presented in the form of statistical tables and graphs. since this study will be conducted in double-blind method, in addition to patients, the anesthesia resident who is the assistant of the project and the intern in charge of the project will be blinded.

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
Research Deputy; Payambar-e-Azam Complex; Basij Square, Sardasht, Arak

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Markazi

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848176941

Approval date
2021-06-23, 1400/04/02

Ethics committee reference number
IR.ARAKMU.REC.1400.057

Health conditions studied

1

Description of health condition studied
Major depressive disorder

ICD-10 code
F32.9

ICD-10 code description
Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description
Mean Arterial Pressure

Timepoint
Beginning and the end of recovery

Method of measurement
Monitor

2

Description
Pulse Rate
Timepoint
Beginning and the end of recovery
Method of measurement
Monitor

3

Description
Pulse oximetry (SpO2)
Timepoint
Beginning and the end of recovery
Method of measurement
Monitor

4

Description
Satisfaction score
Timepoint
After recovery
Method of measurement
questionnaire

5

Description
Agitation Score
Timepoint
After recovery
Method of measurement
questionnaire

6

Description
Duration of seizures
Timepoint
beginning and the end of seizures
Method of measurement
Minutes with chronometer

7

Description
duration of recovery
Timepoint
Beginning and the end of recovery
Method of measurement
Chronometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group B, the anesthesia process is induced by intravenous injection of 0.5 mg / kg Ketamine with 0.5 mg / kg Propofol (Ketofol) and injection of 0.5 mg / kg Succinylcholine and 0.5 mg Atropine in group B.
Category
Treatment - Drugs

2

Description
Control group: In group A, 100 micrograms of Remifentanil is injected intravenously before induction of anesthesia. For bilateral blinding of the study, the amount of drug is increased to 5 CC with normal saline. The anesthesia process is then induced by injection of 2-3 mg / kg Sodium Thiopental , 0.5 mg / kg Succinylcholine and 0.5 mg Atropine in group A.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Web page address

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. Alireza Kamali

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Position

Medical intern

Latest degree

Medical doctor

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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