Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of combination of Propofol-Remifentanil versus Ketofel in duration of seizure and hemodynamic signs of psychotics patient in electroconvulsive therapy

Protocol summary

Study aim
Effect of combination of Propofol-Remifentanil vs Ketofel in duration of seizure and hemodynamic signs of psychotics patient in electroconvulsive therapy

Design
This study is clinical trial and double-blind. 105 psychotics patients for electroconvulsive therapy will be randomly divided into 3 groups. Groups of study are parallel.

Settings and conduct
105 psychotics patients for electroconvulsive therapy referring to Amir Kabir Hospital of Arak are included in this study. The study is double-blind. This study is clinical trial.Researcher who complete questionnaire and analyzer are blind (double blind).Outcome elevator and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18 to 50 years; patients with a diagnosis of major schizophrenia depression of catatonia or bipolar disorder; ASA class I and II Exclusion criteria: Sensitivity to medications used; drug history; history of cardiovascular disease; pregnancy; patients in need of treatment for hemodynamic instability following seizures, who had less than 25 second tonic or clonic seizures, or had more than 60% energy to induce seizures

Intervention groups
Control group: We will inject distilled water and propofol 1 milligram in kilogram. Intervention group:We will inject Remifentanil 1 milligram in kilogram (Produced by Normon Company) and Propofol 1 milligram in kilogram. Intervention group:We will inject Ketamin 1 milligram in kilogram (Ferdows & Razi company) and Propofol 1 milligram in kilogram.

Main outcome variables
Mean arterial pressure, heart rate, arterial oxygen saturation, duration of seizures

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N129**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

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
2019-05-05, 1398/02/15

Expected recruitment end date
2020-05-04, 1399/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of combination of Propofol-Remifentanil versus Ketofel in duration of seizure and hemodynamic signs of psychotics patient in electroconvulsive therapy

Public title
Effect of combination of Propofol-Remifentanil vs Ketofel in duration of seizure and hemodynamic signs of psychotics patient in electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 50 years Patients with a diagnosis of major schizophrenia depression of catatonia or bipolar disorder ASA class I and II
Exclusion criteria:
Sensitivity to medications used Drug history History of cardiovascular disease Pregnancy Patients in need of treatment for hemodynamic instability following seizures, who had less than 25 second tonic or clonic seizures, or had more than 60% energy to induce seizures
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with randomization with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe Arak University Of Medical Sciences
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
848176941
Approval date
2019-04-15, 1398/01/26
Ethics committee reference number
IR.ARAKMU.REC.1398.034

Health conditions studied

1

Description of health condition studied
psychotics patient
ICD-10 code
F06.0
ICD-10 code description
Psychotic disorder with hallucinations due to known physiological condition

Primary outcomes

1

Description
Mean arterial pressure
Timepoint
At baseline, 1, 2, and 3 minutes after shock and after recovery
Method of measurement
Barometer

2

Description
Heart rate
Timepoint
At baseline, 1, 2, and 3 minutes after shock and after recovery
Method of measurement
Count

3

Description
Oxygen saturation percentage
Timepoint
At baseline, 1, 2, and 3 minutes after shock and after recovery
Method of measurement
Pulse oximetry

4

Description
Duration of seizures
Timepoint
After electro convulsive therapy
Method of measurement
Minute

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: We will inject Remifentanil 1 milligram in kilogram (Produced by Normon Company) and Propofol 1 milligram in kilogram.
Category
Treatment - Drugs

2

Description
Intervention group2: We will inject Ketamin 1 milligram in kilogram (Ferdows & Razi company) and Propofol 1 milligram in kilogram.
Category
Treatment - Drugs

3

Description
Control group: We will inject distilled water and propofol 1 milligram in kilogram.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
Dr Bijan Yazdi
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Amirkabir hospital, Parastar square, Arak
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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 Hesamedin Modir

Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 Bijan Yazdi
What processes are involved for a request to access data/document
They have to write letters to the professors and the university
Comments