Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the effects of propofol-remifentanil and ketofol on seizure duration in electroconvulsive therapy

Protocol summary

Study aim
Comparison between the effects of propofol-remifentanil and ketofol on seizure duration in electroconvulsive therapy

Design
This study was conducted in parallel, double-blind, randomized, 40 people who were in the Phase 3 trial were designed

Settings and conduct
Patients are referred to pediatric phychology ward of al-Zahra hospital. The patients are randomly divided into two groups including group A who recieves propofol+ketamine and group B who recieves propofol +remifentanil .and the duration of seizure is detected in each patient. The Participants, Care provider, Outcome assessor, are not aware of the drug type and the investigator deciphers the codes after data analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria : patients candidates receiving electroconvulsive therapy seizures Subjects older than 6 years old and younger than 25 years old American Society of Anesthesiology physical status class 1,2 (ASAI, II) Exclusion criteria: subjects with severe cardiovascular disease, kidney disease, Liver disease, Chronic respiratory disease, drugs Allergy

Intervention groups
For all intervention groups, informed consent is obtained from the parents of patients. Then an appropriate peripheral vein is taken from the patients and the blood pressure and electrocardiography and pulse oximetry devices are connected to the patients, all patients recieve 0.5 mg/kg succinylcholine. Intervention group A recieves 1cc/20kg from a syringe filled with 2.5cc propofol+1cc ketamine + 1.5cc distilled water and intervention group B recieves 1cc/20kg from a syringe filled with 2.5cc propofol+1cc remifentanil +1.5cc distilled water.

Main outcome variables
duration of seizure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N9**
Registration date: **2019-03-18, 1397/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-18, 1397/12/27**
Update count: **0**

Registration date
2019-03-18, 1397/12/27

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3212 3543

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between the effects of propofol-remifentanil and ketofol on seizure duration in electroconvulsive therapy

Public title
The effect of the two drugs propofol-remifentanil and ketofol in electroconvulsive therapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidates receiving electroconvulsive therapy seizures Patients older than 6 yeras old and younger than 25 years old Patients with American society of anesthesiology physical status class 1,2 (ASAI,II)

Exclusion criteria:
Severe cardiovascular disease Severe respiratory disease Severe kidney disease Severe Liver disease drugs Allergy

Age
From **6 years** old to **25 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to two groups A, B using the Random Allocation computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
All drugs are in one form and in the form of a volume in the syringe by the researcher, and the hemodynamic changes are monitored and recorded, so the attending and the clinical caregiver and the evaluator do not understand the type of medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezarjarib street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-05-26, 1396/03/05

Ethics committee reference number
IR.MUI.REC.1396.3.560

Health conditions studied

1

Description of health condition studied
Seizure duration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Seizure duration

Timepoint
After intervention

Method of measurement
In seconds using a chornometer

2

Description
Heart rate changes

Timepoint
Before the intervention, 1 , 5, 10 minutes after intervention and After The discharge time of recovery

Method of measurement
Pulse oximetry device

3

Description
Mean arterial blood pressure

Timepoint
Before the intervention, 1 , 5, 10 minutes after intervention and After The discharge time of recovery

Method of measurement
Non invasive blood pressure

4

Description
Oxygen saturation

Timepoint
Before the intervention, 1 , 5, 10 minutes after intervention and After The discharge time of recovery

Method of measurement
Pulse oximetry device

5

Description
Recovery Duration
Timepoint
From the end of seizure to full consciousness
Method of measurement
Minute with using a chronometer

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
After end of the seizure
Method of measurement
Questionnaire

2

Description
Laryngospasm
Timepoint
After end of the seizure
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group A: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached. In this group 1cc/20kg from a syringe filled with 2.5cc propofol+1cc ketamine + 1.5cc distilled water is injected.
Category
Treatment - Drugs

2

Description
Intervention group B: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached. In this group 1cc/20kg from a syringe filled with 2.5cc propofol+1cc remifentanil + 1.5cc distilled water is injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Behzad Nazemroaya
Street address
Soffeh boulivard, Shahid Kesari highway
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Shirin hashemi fesharaki
Position
Medical student/ Intern
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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available