

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effect of low dose Ketamine and Midazolam injection with low dose Ketamine and Dexmedetomidine on changes in heart rate and blood pressure in Electroconvulsive therapy

Protocol summary

Study aim

Introducing an ideal method for controlling blood pressure, heart rate and respiratory parameters during various surgeries, especially electroconvulsive therapy

Design

Clinical trial with parallel, double-blind, randomized, phase 2 groups on 70 patients. Randomization is simple and patients are admitted to one of the two groups according to the time of admission.

Settings and conduct

This trial will be performed in the ECT ward of Al-Zahra Hospital in Isfahan; In this way, after obtaining permission from the University Medical Ethics Committee and obtaining patient satisfaction, 70 patients are selected as candidates for electroconvulsive therapy and randomly distributed in two groups of 35 people and each group will be injected with one of the therapeutic interventions. The patient's vital signs will be recorded. Patients and clinical caregivers are unaware of the injected drug and are blind.

Participants/Inclusion and exclusion criteria

All patients 18 to 65 years old who are candidates for electroconvulsive therapy who do not have a history of a specific disease can be included in the study if they agree.

Intervention groups

Intervention group A; 0.1 mg / kg ketamine with 0.04 mg / kg midazolam and intervention group B; They receive 0.1 mg / kg ketamine at a dose of 0.5 µg / kg dexmedetomidine before induction of anesthesia.

Main outcome variables

Heart Rate; Blood Pressure, Oxygen Saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N23**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **prospective**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

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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behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of low dose Ketamine and

Midazolam injection with low dose Ketamine and Dexmedetomidine on changes in heart rate and blood pressure in Electroconvulsive therapy

Public title

The effect of the combination of Ketamine and Midazolam as well as a combination of ketamine and dexmedetomidine in Electroshock therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for Electroconvulsive Therapy Age 18 to 65 Patient consent to study

Exclusion criteria:

History of drug allergy History of cardiovascular disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is a simple method; In this way, the first patient is assigned to one of the groups by lottery and the next patients are distributed consecutively and one in between in two groups so that the sample size reaches the required number in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding is that patients are unaware of the type of drug received and also the executor of the project will be unaware of the type of injectable drug to patients. In this way, the drugs are prepared and coded in similar syringes by one of the operating room personnel who is not in the process of study, and are given to the executor for injection.

Placebo

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

Hezar jarib street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-05-27, 1399/03/07

Ethics committee reference number

IR.MUI.MED.REC.1399.377

Health conditions studied

1

Description of health condition studied

ElectroConvulsive Therapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart Rate

Timepoint

Before drug injection, after drug injection, after shock termination, 5 and 10 minutes after end of seizure

Method of measurement

ECG monitoring

2

Description

Blood Pressure

Timepoint

Before drug injection, after drug injection, after shock termination, 5 and 10 minutes after end of seizure

Method of measurement

Non-invasive blood pressure measurement

3

Description

Oxygen Saturation

Timepoint

Before drug injection, after drug injection, after shock termination, 5 and 10 minutes after end of seizure

Method of measurement

Pulse Oxymeter

Secondary outcomes

1

Description

Duration of seizures

Timepoint

From the beginning to the end of the seizure

Method of measurement

Chronometer

2

Description

Complications after anesthesia

Timepoint

From the time of drug discontinuation to the end of recovery

Method of measurement

View patient status

3

Description

Recovery time

Timepoint

From stopping the drug to full consciousness

Method of measurement

Chronometer

Intervention groups

1

Description

Intervention group A: The patient will receive 0.1 mg / kg of Ketamine and 0.04 mg / kg of Midazolam.

Category

Treatment - Drugs

2

Description

Intervention group B: The patient will receive 0.1 mg per kg bodyweight of Ketamine and 0.5 micrograms per kg body weight of Dexmedetomidine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazemoroaya

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice Chancellor for Research, Isfahan 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

Zahra Manian

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Full name of responsible person

Behzad Nazem roaya

Position

Professor assistant of Anesthesia and Intensive care intensive care

Latest degree

Specialist

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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