

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Survey the effectiveness of ketamine on myalgia, headache and agitation in Major Depression patients after electroconvulsive therapy.

#### Protocol summary

##### Summary

This is a double blind, randomized, mono center, clinical trial with a placebo control group that will be performed in Quads hospital, Sanandaj ,Iran. Inclusion criteria include: major depression based on DSM 4 criteria, physical condition in accordance with ASA Class 1 or 2, and ability and capacity to sign informed consent sheet and exclusion criteria includes: history of major systemic disease, neuromuscular disease, and myalgia. Calculated sample size is 50 patients who will be divide randomly in two groups: Ketamine (study) and normal saline (control). Each patient will be studied at the second and third ECT sessions in a crossover method. Ketamine 30 mg or 2ml 0, 09% saline will be injected in first study ECT session and vice versa in the next ECT session in zero time. Atropine (0.5 mg) will be injected one minute later followed by induction of anesthesia with 1 mg/kg propofol at 30 second later; muscle paralysis will be achieved with 0.5 mg/kg succinylcholine. After reaching paralysis convulsion will be induced by electrical stimulation with first ECT energy doses. Seizure duration, mean arterial pressure and heart rate (at three time: pre-induction, post-induction, and post seizure) myalgia (at 6, 12, 24, and 48 hour after ECT) occurrence of headache and agitation at 24 hour after ECT will be evaluated and be recorded too.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904221766N4**

Registration date: **2011-11-19, 1390/08/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

**Registration date**

2011-11-19, 1390/08/28

##### Registrant information

###### Name

Karim Nasseri

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 1666 3728

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##### Recruitment status

**Recruitment complete**

##### Funding source

Kurdistan University of Medical Sciences

##### Expected recruitment start date

2011-10-16, 1390/07/24

##### Expected recruitment end date

2012-10-15, 1391/07/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Survey the effectiveness of ketamine on myalgia, headache and agitation in Major Depression patients after electroconvulsive therapy.

##### Public title

Evaluating the effectiveness of ketamine on muscle pain (myalgia), headache and restlessness (agitation) after electroconvulsive therapy in patients with major depression disorder.

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

Inclusion criteria: Major depression based on DSM 4 criteria, physical condition in accordance with ASA Class 1 or 2, ability and capacity to sign informed consent sheet. Exclusion criteria: history of major systemic disease, history of neuromuscular disease, history of myalgia.

## **Age**

From **18 years** old to **70 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **50**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

## **Placebo**

Used

## **Assignment**

Crossover

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kurdistan University of Medical Sciences

##### **Street address**

Pasdaran BLV , Pardis of University

##### **City**

Sanandaj

##### **Postal code**

#### **Approval date**

2011-10-15, 1390/07/23

#### **Ethics committee reference number**

14/2018

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Electroconvulsive therapy induced myalgia

#### **ICD-10 code**

M79.1

#### **ICD-10 code description**

Myalgia

## **Primary outcomes**

### 1

#### **Description**

Myalgia

#### **Timepoint**

At 6, 12, 24 and 48 hours after ECT

#### **Method of measurement**

Myalgia graded as follow: absence of myalgia = no; stiffness or muscle pain did not need treatment = mild; muscle pain or stiffness reported spontaneously by the patient, and required therapy = moderate; very severe discomfort = severe

### 2

#### **Description**

Headache

#### **Timepoint**

In the first 24 hours after ECT

#### **Method of measurement**

Visual Analogue Scale

### 3

#### **Description**

Agitation

#### **Timepoint**

In the recovery period

#### **Method of measurement**

1. Yes: motor restlessness, severe motor movement, and besides, un-aimed try to leave the bed, wanting to get up from bed, high loud crying, pulling catheters, confusion and poor response to verbal commands) 2 . No: not mentioned in any of the above scenarios

## **Secondary outcomes**

### 1

#### **Description**

Seizure duration

#### **Timepoint**

After induction of ECT

#### **Method of measurement**

Second

### 2

#### **Description**

Mean arteial blood pressure

#### **Timepoint**

Before induction of anesthesia ,after induction of anesthesia ,and after termination of seizure

#### **Method of measurement**

Millimeter of Hg

### 3

#### **Description**

Heart Rate

#### **Timepoint**

Before induction of anesthesia , after induction of anesthesia ,and after termination of seizure

**Method of measurement**

Beat /minute

**Intervention groups**

**1**

**Description**

Control group: In this group 2 ml normal saline (placebo) will be injected before any other drugs in zero time.

**Category**

Prevention

**2**

**Description**

Study group: In this group 30 Mg Ketamine that had been diluted in 2 ml normal saline will be injected before any other drugs in zero time.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Quads Hospital

**Full name of responsible person**

Dr Karim Nasseri

**Street address**

Niroy Entezami BLV

**City**

Sanandaj

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Ataollah heydari

**Street address**

Faculty of Medicine ,Pasdaran BLV

**City**

Sanandaj

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kurdistan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Faculty of Medicine

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*