Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Electroconvoulsive 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 Analoge 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 preasure
Timepoint
Befor induction of anesthesia ,after induction of anesthesia ,and after termination of seizure
Method of measurement
Milimeter of Hg

3

Description
Heart Rate
Timepoint

Befor 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

Ataaollah 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

Full name of responsible person

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Position

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Other areas of specialty/work

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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