Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparing effects of ketamine and thiopental sodium on depression, cognition and duration of seizure in depressive patients undergoing electroconvulsive therapy.

Protocol summary

Summary

This is a double blind randomized controlled trial which has been approved by the ethic committee of the Tehran University of Medical Sciences. In this study the therapeutic effects and cognitive adverse effects of ketamine and thiopental as the anesthetic agent in electroconvulsive therapy is evaluated in 30 patients (in two groups of 15 patients) between 20-50 years, in whom the diagnosis of major depressive disorder has been confirmed according to the Statistical Manual of Mental Disorder, Fourth Edition Text Revision and Hamilton depression rating scale of 18 or more and are planned to receive electroconvulsive therapy and signing the inform consent . On the day before the first ECT all subjects undergo pre-ECT medical evaluations. Hamilton depression rating scale and mini–mental state examination are also performed. Patients will randomly be assigned to receive either ketamine (1-2 mg/kg) or thiopental (2-3 mg/kg) as the anesthetic agent for the electroconvulsive therapy. All patients receive atropine before induction of anesthesia. After the induction of anesthesia, succinylcholine is administered as muscle relaxant. Respiratory supportive measures are administered with oxygen through bag and mask. Then dose titration according to age is used for the electroconvulsive therapy. In each session seizure time, heart rate , blood pressure are measured. The assessment of cognition and depression is repeated before the second ECT, 3-7 days after the 6th treatment and one month after that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201247202N3**

Registration date: **2013-02-25, 1391/12/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

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Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of ketamine and thiopental sodium on depression, cognition and duration of seizure in depressive patients undergoing electroconvulsive

therapy.

Public title
Effects of ketamine and thiopental sodium on depression, cognition and duration of seizure in patients undergoing electroconvulsive therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria : MDD(diagnosed on the basis of DSM IV criteria) ;HAM-D score greater than 18 Exclusion Criteria: History of any serious underlying conditions (active CV or renal insufficiency); neurological disorders (bulky mass or history of seizure disorders); other psychiatric diagnosis such as schizophrenia, schizoform or schizoaffective disorders, bipolar affective disorder; history of drug abuse in past six months; receiving electroconvulsive therapy in the past 6 months, verbal or auditory disorders (for ability to perform diagnostic tests)
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences (TUMS)
Street address
Keshavarz BLVD
City
Tehran
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
2886

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
f 32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Changes in depression severity
Timepoint
before the first and second and after the 6th sessions of electroconvulsive therapy and 1 month after that
Method of measurement
Hamilton Rating Scale for Depression

Secondary outcomes

1

Description
cognitive function
Timepoint
before the first and second electroconvulsive therapy ,after the 6th and 1 month after that
Method of measurement
Mini–mental state examination

2

Description
seizure duration
Timepoint
in every ECT session
Method of measurement
chronometer

3

Description
hemodynamic changes (blood presure, heart rate)
Timepoint
brfore and after each electroconvulsive therapy session
Method of measurement
pulseoxymeter, sphyngomanometer

Intervention groups

1

Description
Patients in this group receive thiopental (bolus 2-3 mg/kg) as anesthetic agent for 6 electroconvulsive treatment
Category

Treatment - Drugs

2

Description
Patients in this group receive ketamine (bolus 1-2 mg/kg) as anesthetic agent for 6 electroconvulsive treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Street address
South Kargar Ave
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akhondzadeh, Vice- Chancellor for Reseach of School of Medicine
Street address
School of Medicine, Tehran University of Medical Sciences,16th Azar Street
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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Name of organization / entity
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Person responsible for updating data

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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