

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

pghaeli@sina.tums.ac.ir

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

City

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

Contact

Name of organization / entity

Faculty of Pharmacy, Tehran University of Medical

Sciences

Full name of responsible person

Dr Padideh Ghaeli

Position

Associate Professor of Clinical Pharmacy, Tehran University of Medical Sciences

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16th Azar Street

City

Tehran

Postal code

Phone

+98 21 6695 4709

Fax

Email

mmpgg@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Abolghasem Yousefi

Position

Assistant Professor of Anesthesiology, Tehran University of Medical Sciences

Other areas of specialty/work

Street address

Department of Anesthesiology, Amiralam Hospital

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

yousefi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person

Dr Mona Kargar

Position

Pharm.D, Clinical Pharmacy Resident

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16th Azar Street

City

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Fax

+98 21 6695 4709

Email

mkargar@razi.tums.ac.ir

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