

# 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

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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

**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

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Associate Professor of Clinical Pharmacy, Tehran University of Medical Sciences

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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*