Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative clinical trial of induction of anesthesia with midazolam and Sodium Thiopental versus Thiopental alone in patients which are candidates for Electroconvulsive therapy

Protocol summary

Summary

The aim of this clinical trial is comparison of induction of anesthesia with midazolam and Sodium Thiopental and Sodium Thiopental alone, in patients selected for Electroconvulsive therapy (ECT). Inclusion criteria: patients with major depression; age over 18 year. Exclusion criteria: air way obstruction; obesity; somnolence; kidney and hepatic failure; muscle weakness; severe asthma; all ECT contraindications; patient's discontent. This is a clinical trial on 60 subjects who are selected for this study by agreement of a psychiatric. History taking and necessary examinations are done the night before ECT. These subjects are divided into two groups of 30 ones (15 male and 15 female). At the time of entrance to ECT room, their vital signs are measured and documented. In group A, Sodium Thiopental (3 mg/Kg) is injected for induction and in group B, Sodium Thiopental (1.5 mg/Kg) and midazolam (2.5 mg) are administered. In both groups Succinylcholine (0.5 mg/kg) is used for relaxation. After induction of anesthesia, standard dose of electroshock is given by psychiatric, and starting and ending point of convulsion is measured by chronometer. The subject is referred to recovery room following returning of breathing and securing vital signs, and remained until orientation recovery. Duration of anesthesia and recovery period are measured and documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013010741N2**
Registration date: **2016-02-11, 1394/11/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-11, 1394/11/22

Registrant information

Name

Minoo Ghahraman

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 1211 5814

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research; Kerman University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative clinical trial of induction of anesthesia with midazolam and Sodium Thiopental versus Thiopental alone in patients which are candidates for Electroconvulsive therapy

Public title

Comparison of induction of anesthesia with midazolam and Sodium Thiopental and Sodium Thiopental alone, in Electroconvulsive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with major depression; age over 18 year. Exclusion criteria: air way obstruction; obesity; somnolence; kidney and hepatic failure; muscle weakness; severe asthma; all ECT contraindications; patient's discontent.

Age

From **17 years** old to **139 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University Medical Sciences

Street address

Shafa Square

City

Kerman

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

k/93/700

Health conditions studied

1

Description of health condition studied

Recurrent depressive disorder

ICD-10 code

F33

ICD-10 code description

Recurrent depressive disorder

Primary outcomes

1

Description

seizure duration

Timepoint

after giving shock

Method of measurement

Chronometer

2

Description

Recovery duration

Timepoint

after giving shock

Method of measurement

Chronometer

3

Description

anesthesia duration

Timepoint

after giving shock

Method of measurement

Chronometer

Secondary outcomes

1

Description

vital sign

Timepoint

during the session

Method of measurement

monitoring device

Intervention groups

1

Description

In group A, Sodium Thiopental (3 mg/Kg-IV) is injected for induction of anesthesia

Category

Treatment - Drugs

2

Description

in group B, patients receive intravenous Sodium Thiopental (1.5 mg/Kg) and midazolam (2.5 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
SHAHID BEHESHTI HOSPITAL
Full name of responsible person
SAHA MEHRABI
Street address
Jomhouri Blvd.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman 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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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