Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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

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Name of organization / entity
Kerman University of Medical Sciences
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Iran (Islamic Republic of)
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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
Kerman

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