Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of anesthesia with combined Remifentanil and Propofol in electroconvoulsive therapy on efficacy, cognitive effects and seizure duration in patients with severe mania

Protocol summary

Summary

The purpose of this study is to examine the impact of anesthesia with combined Remifentanil and Propofol on efficacy and cognitive effects in patients with severe mania. 32 participants will be recruited from consecutive inpatients, diagnosed to have a manic episode by DSM-IV criteria, who were prescribed ECT by their clinicians. Patients undergo administration of either Remifentanil (100 µg) plus Atropine 0.5 mg (study) or saline plus Atropine 0.5 mg (control) always adjusted to a 2-ml volume according to the patient's group; Severity of mania will be assessed by the Young Mania Rating Scale (YMRS) and cognitive side effects will be assessed by Mini-Mental State Examination (MMSE). Immediate cognitive side effects will be assessed by measuring post –treatment reorientation time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810082935N1**
Registration date: **2010-01-25, 1388/11/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-01-25, 1388/11/05

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of anesthesia with combined Remifentanil and Propofol in electroconvoulsive therapy on efficacy, cognitive effects and seizure duration in patients with severe mania

Public title

Combined Remifentanil and Propofol in electroconvulsive therapy of acute mania

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: (1) a history of ECT during the preceding 6-month period; (2) use of nonbenzodiazepine anticonvulsants (valproate, carbamazepine, lamotrigine, or topiramate), lidocaine, theophylline, or lithium during the last week; (3) a history of rapid-cycling or mixed bipolar illness, schizophrenia, or another psychotic disorder that was not part of the mood disorder; (4)

neurological illness or severe medical illness, 5) pregnancy, 6) stroke within the past 3 months, 7) brain surgery 8) severe head trauma, 9) drug or alcohol dependence within the past 2 years. 10)seizure duration more than 90 seconds in each episodes of ECT. Inclusion criteria: 1) diagnosis by Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) (American Psychiatric Association, 2000), of a bipolar I disorder (manic episode) 2) age between 18 to 45 years old 3) The minimal score on Young Mani Rating Scale (YMRS)≥20 4) Signed informed consent 5) IQ>70 6) ASA class 1 or 2

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kurdistan University of Kurdistan

Street address
Pasdaran Blvd-Kurdistan University of Medical Sciences

City
Sanandaj

Postal code

Approval date
2009-08-06, 1388/05/15

Ethics committee reference number
668

Health conditions studied

1

Description of health condition studied
bipolar disorder type one

ICD-10 code
F31

ICD-10 code description
Bipolar affective disorder

Primary outcomes

1

Description
Severity of mania

Timepoint
baseline and one day after the third, the sixth, and the last ECT sessions

Method of measurement
Young Mania Rating Scale (YMRS)

2

Description
Cognitive status

Timepoint
Mini-Mental State Examination (MMSE)

Method of measurement
baseline and one day after the third, the sixth, and the last ECT sessions

3

Description
Orientation

Timepoint
once subjects will be removed into the recovery room and will be repeated every 15 minutes

Method of measurement
post –treatment reorientation time test

Secondary outcomes

1

Description
Duration of seizure

Timepoint
during each session of ECT

Method of measurement
mesurement of duration of seizure

Intervention groups

1

Description
Remifentanil (100 µg) plus Atropine 0.5 mg (study) for induction of anesthesia before injection of Propofol

Category
Treatment - Drugs

2

Description
Saline plus Atropine 0.5 mg for induction of anesthesia

before injection of Propofol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qhods hospital- Sanandaj

Full name of responsible person

Dr Farzin Rezaei

Street address

Pasdaran Blvd- Qhods hospital - Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

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City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Farzin Rezaei

Position

psychiatrist-assistant professor

Other areas of specialty/work

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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