

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation the effect of anesthesia with combined Remifentanil and Propofol in electroconvulsive 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

##### Name

Farzin Rezaei

##### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 1356 1822

##### Email address

farrezaei@muk.ac.ir

##### 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 electroconvulsive 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 Mania 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**

Pasdarán 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**

measurement of duration of seizure

### **Intervention groups**

#### **1**

##### **Description**

Remifentanyl (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  
**Street address**  
Pasdaran Blvd-Kurdistan university of Medical  
Sciences-Deputy of research- SANANDA  
**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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*