

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effects of Naltrexone versus placebo on memory deficit followed by Electroconvulsive therapy in depressed patients: A double blind clinical trial

#### Protocol summary

##### Summary

Electroconvulsive therapy (ECT) is famously known as a treatment for psychiatric disorders as in particular depressive illness. In this regard, memory impairments have always been a focus of concern. Various pharmacological agents have been studied to assess their possible effect in attenuation of memory and other cognitive adverse effects. In this randomized placebo-controlled study 40 depressed patients aged 18 to 65, candidate for six ECT sessions, who met DSM IV criteria for Major Depressive Episode were eligible. The effect of capsule Naltrexone versus placebo which is prescribed the night before ECT sessions, in memory deficit induced by ECT is being assessed. The Wechsler memory questionnaire will be filled out by face to face interview with patients, at the day before ECT sessions, two weeks, one month and three months after ECT sessions. Hamilton Depression Rating Scale will also be filled out before and 3 months after ECT session.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016060628309N1**

Registration date: **2016-09-02, 1395/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-02, 1395/06/12

##### Registrant information

##### Name

Somayeh Motazedian

##### Name of organization / entity

Fasa University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 301 2895

##### Email address

so.motazedian@fums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2012-03-19, 1390/12/29

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of Naltrexone versus placebo on memory deficit followed by Electroconvulsive therapy in depressed patients: A double blind clinical trial

##### Public title

The effect of Naltrexone on memory deficit induced by Electroconvulsive therapy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : aged 18 to 65 years; major depression or bipolar depression disorder patients based on DSM4 criteria; indicated for ECT Exclusion criteria: affected by a prominent medical condition; diagnosed with

schizophrenia or mania; a history of ECT in the last 6 month; recent opioid use

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Random number Table

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti Medical University

##### Street address

Shahid Beheshti Medical University, Tehran

##### City

Tehran

##### Postal code

#### Approval date

2011-09-24, 1390/07/02

#### Ethics committee reference number

9169

## Health conditions studied

### 1

#### Description of health condition studied

Depressive Episode

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

### 2

#### Description of health condition studied

Memory deficit induced by electroconvulsive therapy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Memory deficit

#### Timepoint

At the day before ECT sessions, two weeks, one month and three months after ECT sessions

#### Method of measurement

Wechsler memory test

## Secondary outcomes

### 1

#### Description

Depression severity

#### Timepoint

Before and 3 months after ECT session

#### Method of measurement

Hamilton Depression Questionair

## Intervention groups

### 1

#### Description

Intervention Group: Naltrexone cap 50 mg , The night before ECT session

#### Category

Treatment - Drugs

### 2

#### Description

Control Group: Placebo Capsule The afternoon before ECT session

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Psychiatry, Imam Hossein Hospital

##### Full name of responsible person

##### Street address

**City**  
Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Shahid Beheshti  
University of Medical Sciences

**Full name of responsible person**  
Alireza Zahiroddin

**Street address**  
Imam Hossein Hospital, Shahid Madani St. Tehran

**City**  
Tehran

#### 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, Shahid Beheshti 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**  
Fasa university of medical sciences

**Full name of responsible person**  
Somayeh Motazedian

**Position**  
Psychiatrist

#### Other areas of specialty/work

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Psychiatric Department. Dr Ali Shariati Hospital, Fasa

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## Person responsible for scientific

## inquiries

#### Contact

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**Full name of responsible person**  
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Professor

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## Person responsible for updating data

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#### Fax

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so.motazedian@fums.ac.ir

#### Web page address

## 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*