

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of the effect of the synchronised exercise and electroconvulsive therapy on serum brain neurotrophic factor in drug resistance depressive patient

#### Protocol summary

##### Summary

This was a double-blind clinical trial as a comparative study to evaluate the serum level of brain-derived neurotrophic factor in patients with unipolar major depressive disorder treated with electroconvulsive+antidepressant, exercises +antidepressant and antidepressants only who have been admitted in one of the psychiatric wards of Farshchian Hospital, Hamadan. In this study, there are 60 admitted patients at the age of 18-40 years who have no systemic disease and no illegal substance abuse; they will be enrolled in the study with informed consent and will be divided into 3 groups based on randomized blocks. The first group will undergo electroconvulsive+ antidepressant, second group exercise +antidepressant, and other antidepressant only. Before the treatment and fourth week after it Hamilton depression Rating scale will be completed by all the patients and patients' blood samples will also be collected in a similar method to measure the serum level of brain-derived neurotrophic factor. Their factor rate and depression intensity will be monitored too.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312271743N12**

Registration date: **2014-01-07, 1392/10/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-01-07, 1392/10/17

##### Registrant information

##### Name

Mohammad Haghighi

##### Name of organization / entity

Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1827 4184

##### Email address

haghighi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamadan University of Medical Sciences

##### Expected recruitment start date

2013-01-01, 1391/10/12

##### Expected recruitment end date

2013-06-01, 1392/03/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of the synchronised exercise and electroconvulsive therapy on serum brain neurotrophic factor in drug resistance depressive patient

##### Public title

Brain-Derived Neurotrophic Factor level in Depressive patients

##### Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusive Criteria 1. Patients with unipolar major depressive disorder admitted in one of the psychiatric wards of Farshchian Hospital 2. Aged of 18-40 years 3. No systemic diseases such as diabetes, hypertension, epilepsy and etc 4. No history of alcohol abuse or other illegal substances 5. Patient's informed consent  
Exclusive Criteria 1. Incidence of uncontrollable somatic condition 2. Patient's unwillingness to continue participation

## Age

From **18 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## 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

Hamadan University of Medical Sciences

### Street address

Fahmideh str.

### City

Hamadan

### Postal code

## Approval date

2009-05-05, 1388/02/15

## Ethics committee reference number

18366/9/35/پ

## Health conditions studied

### 1

## Description of health condition studied

Major Depressive Disorder

## ICD-10 code

F32

## ICD-10 code description

Depressive episode

## Primary outcomes

### 1

## Description

Severity of symptoms of Depression

## Timepoint

Baseline and 4 weeks after treatment

## Method of measurement

Hamiltone Depression scale

### 2

## Description

level of Brain-derived neurotrophic factor in serum

## Timepoint

Baseline and 4 weeks after treatment

## Method of measurement

ELISA

## Secondary outcomes

empty

## Intervention groups

### 1

## Description

Electero Convulsive Therapy+ antidepressant drug

## Category

Treatment - Drugs

### 2

## Description

exercise +antidepressant

## Category

Treatment - Drugs

### 3

## Description

Antidepressant drug

## Category

Treatment - Drugs

## Recruitment centers

### 1

## Recruitment center

### Name of recruitment center

Farshchian Hospital

### Full name of responsible person

Mohammad Haghighi

### Street address

### City

Hamadan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

**Full name of responsible person**

Mohammad Haghighi

**Street address**

honarestan Str.

**City**

Hamadan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center for behavioral disorders and substance abuse, Hamadan 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**

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

**Full name of responsible person**

Mohammad Haghighi

**Position**

Associate professor

**Other areas of specialty/work****Street address**

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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

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Mohammad Haghighi

**Position**

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**Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****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*