

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison of the side effects of treatment with Duloxetine plus Electroconvulsive therapy and Sertraline plus Electroconvulsive therapy in patients with treatment resistant major depression

#### Protocol summary

##### Study aim

Assurance of safety of therapeutic combination of duloxetine plus electroconvulsive therapy

##### Design

The clinical trial in phase I is allocated to two 16 member groups selected by randomization software treated with duloxetine and sertraline, after making sure of existence of inclusion criteria and lack of exclusion criteria Electrocardiography is taken from each of them and Electroconvulsive therapy is applied. During ECT the duration of the seizures are recorded. Then the EKG is repeated again and any complaint including nausea, headache and body pain is asked and recorded. Before and after seizure cognitive state of any individual is evaluated by MMSE. Any differences in all variables are recorded and compared between the two groups.

##### Settings and conduct

The patients are randomly chosen among treatment resistant depressed patients candidates for ECT admitted in Shiraz Ebne Sina Hospital. Surveillance of possible side effects recorded in the intervention group.

##### Participants/Inclusion and exclusion criteria

Treatment resistant depression, Age between 20 to 60 years without other medical condition, neurological disorder, cardiovascular disease, contraindication to duloxetine and/ or Sertraline, Using other antidepressant(s) or drugs with possible effect on ECT and any contraindication for ECT, Sertraline and/or duloxetine

##### Intervention groups

Electroconvulsive therapy plus duloxetine group,  
Electroconvulsive therapy plus sertraline group

##### Main outcome variables

Convulsion duration; electrocardiogram; headache; body pain; nausea; cognition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181204041847N1**

Registration date: **2018-12-17, 1397/09/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-17, 1397/09/26**

Update count: **0**

##### Registration date

2018-12-17, 1397/09/26

##### Registrant information

##### Name

Ebrahim Moghimi-Sarani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 9319

##### Email address

moghimie@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-10, 1397/09/19

##### Expected recruitment end date

2019-02-10, 1397/11/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the side effects of treatment with Duloxetine plus Electroconvulsive therapy and Sertraline plus Electroconvulsive therapy in patients with treatment resistant major depression

## Public title

Side effects of Duloxetine plus Electroconvulsive therapy in depression

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Treatment resistance depression diagnosed by psychiatrist based on DSM5 criteria

### Exclusion criteria:

Other medical condition Neurological disorder Cardiovascular disease Contraindication to duloxetine and/ or Sertraline Current using other antidepressant(s) or drugs with possible effect on ECT Any contraindication for ECT

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization with bio-statistical software

## 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 Shiraz University of Medical Sciences

##### Street address

Zand Street, Shiraz University of Medical Sciences

##### City

Shiraz

##### Province

Fars

## Postal code

71348-14336

## Approval date

2017-06-14, 1396/03/24

## Ethics committee reference number

IR.SUMS.MED.REC.1396.60

## Health conditions studied

### 1

#### Description of health condition studied

Treatment resistance depression diagnosed by psychiatrist based on DSM5 criteria

#### ICD-10 code

F32.2

#### ICD-10 code description

Severe depressive episode without psychotic symptoms

## Primary outcomes

### 1

#### Description

Convulsion duration

#### Timepoint

During ECT

#### Method of measurement

Time duration with timer

### 2

#### Description

Electrocardiogram

#### Timepoint

Before and after each ECT

#### Method of measurement

Electrocardiogram

### 3

#### Description

Headache

#### Timepoint

After each ECT

#### Method of measurement

History

### 4

#### Description

Cognition

#### Timepoint

Before and after ECT

#### Method of measurement

Mini mental status examination

### 5

#### Description

Body pain

#### Timepoint

After each ECT  
**Method of measurement**  
History

6

**Description**

Nausea

**Timepoint**

After each ECT

**Method of measurement**

History

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Duloxetine plus Electroconvulsive therapy

**Category**

Treatment - Drugs

2

**Description**

Control group: Serteralin plus Electroconvulsive therapy

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ebnesina Hospital

**Full name of responsible person**

Ebrahim Moghimi-Sarani

**Street address**

Hafez Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7144676549

**Phone**

+98 71 3227 1387

**Email**

moghimie@sums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ebrahim MOGHIMI-Sarani

**Street address**

Zand Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3230 5410

**Email**

moghimie@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ebrahim Moghimi-Sarani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Hafez street

**City**

Shiraz

**Province**

Fars

**Postal code**

7144676549

**Phone**

+98 71 3227 1387

**Email**

moghimie@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ebrahim Moghimi-Sarani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Hafez street

**City**

Shiraz

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**Email**

moghimie@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ebrahim Moghimi-Sarani

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Hafez stret

**City**

Shiraz

**Province**

Fars

**Postal code**

7146676549

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of personal Data

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Only a part of data including major outcomes are shared.

**When the data will become available and for how long**

6 month after the publication of results

**To whom data/document is available**

Publishing of the data can be confidential submitted by written request of the ethics committee

**Under which criteria data/document could be used**

Only for Ethics Committee

**From where data/document is obtainable**

Ebrahim moghimi-Sarani

**What processes are involved for a request to access data/document**

written letter of the ethics committee

**Comments**