

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

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Hafez Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

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Person responsible for updating data

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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