

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluating the efficacy of adding rivastigmin to a selective serotonin re-uptake inhibitor, Sertraline, in the treatment of major depressive disorder :a pilot study

Protocol summary

Summary

The aim of this study is to evaluate efficacy and safety of adding rivastigmin to sertraline to improve memory and depressive symptoms in patients with major depression. Twenty outpatients with Major Depressive Disorder based on DSM-V will be included and randomly divided into the intervention and control groups. Subjects in the intervention group receive rivastigmin with an initial dose of 1.5 mg/day from first to third days, which is increased to 3 mg/day on the fourth day and continue with the same dose until the end of the study along with sertraline for three months. The control group receive sertraline with placebo for three months. All depressive patients are managed based on the guidelines of the American Psychiatric Association. The diagnosis is made by two psychiatrists independently, according to the DSM-V criteria. The dose of sertraline will be remained constant during the study period and only co-medication with benzodiazepines is allowed. Wechsler Memory Scale, designed to measure intelligence in adults and older adolescents, and the Hamilton Depression Rating Scale, "Gold Standard" for rating depression in clinical research, are assessed at the baseline and on the third month. Side effects will be assessed with direct questions and observing main complications weekly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020132236N4**

Registration date: **2017-03-05, 1395/12/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

Name

Narjes Hendouei

Name of organization / entity

Department of Pharmacotherapy, Faculty of Pharmacy and Psychiatry and Behavioral Sciences Research C

Country

Iran (Islamic Republic of)

Phone

+98 911 327 0107

Email address

nhendoei@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of adding rivastigmin to a selective serotonin re-uptake inhibitor, Sertraline, in the treatment of major depressive disorder :a pilot study

Public title

Efficacy of rivastigmin in the treatment of major

depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All outpatients with Major Depressive Disorder based on DSM-IV-TR in the age range of 25-55 year old who refer to psychiatric clinic in Imam khomeini hospital clinic. Exclusions criteria: Psychiatric comorbidity(primary or secondary diagnosis of bipolar I disorder, either manic or mixed episode, as defined by DSM-V);History of substance dependence (including alcohol, but excluding nicotine) as defined by DSM-V and relapse within the past 6 months, or substance abuse within the 3 months preceding the trial or positive urine test for illicit drugs;Electroconvulsive therapy during the 6 past months;Suicidality(active suicide or homicide intent, or a suicide or homicide attempt in the preceding 6 months);Mental retardation;Pregnant or at risk of pregnancy; Cognitive disorders such as dementia, delirium, or amnesia, traumatic brain injury;Current significant unstable medical illness (such as unstable cardiac disease, hepatic or renal impairment, evidence or history of malignancy or any significant hematological, endocrine)/ HIV infection / abnormalities on physical examination, vital signs, electrocardiogram (ECG), or clinical laboratory values;Hypersensitivity to rivastigmin;Previous treatment with rivastigmin in the past year; History of neuroleptic malignant syndrome;Patients under treatment cholinesterase inhibitors, N-methyl D-aspartate (NMDA) receptor antagonists;Unwilling or unable, in the opinion of the Investigator, to comply with study instructions

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Ethical committee of Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

Street address

Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences

City

Sari

Postal code

Approval date

2014-09-07, 1393/06/16

Ethics committee reference number

16/6/1393

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode

Primary outcomes

1

Description

Memory

Timepoint

At the baseline and on the third month

Method of measurement

Wechsler Memory Scale

Secondary outcomes

1

Description

Depression severity assessment

Timepoint

At the baseline and on the third month

Method of measurement

Hamilton Depression Rating Scale

2

Description

Rivastigmin side effects

Timepoint

Weekly

Method of measurement

With direct questions and observing main complications

Intervention groups

1

Description

The control group receive sertraline with placebo for three months.

Category

Placebo

2

Description

Subjects in the intervention group receive rivastigmin with an initial dose of 1.5 mg/day from first to third days, which is increased to 3 mg/day on the fourth day and continue with the same dose until the end of the study along with sertraline for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital-Psychiatry clinic

Full name of responsible person

Narjes Hendouei

Street address

Imam Khomeini hospital, Razi street

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences

City

Sari

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, Mazandaran 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

Department of Pharmacotherapy, Faculty of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Narjes Hendouei

Position

Assistant professor

Other areas of specialty/work

Street address

Department of Pharmacotherapy, Faculty of Pharmacy, Mazandaran University of Medical Sciences, 17 Km Sea road

City

Sari

Postal code

Phone

+98 11 3354 3081

Fax

Email

hendoieen@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Pharmacotherapy, Faculty of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Narjes Hendouei

Position

Assistant professor

Other areas of specialty/work

Street address

Department of Pharmacotherapy, Faculty of Pharmacy, Mazandaran University of Medical Sciences, 17 Km Sea road

City

Sari

Postal code

Phone

+98 11 3354 3081

Fax

Email

hendoieen@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Pharmacotherapy, Faculty of

Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Narjes Hendouei

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of Pharmacotherapy, Faculty of
Pharmacy, Mazandaran University of Medical Sciences,
17 Km Sea road

City

Sari

Postal code

Phone

+98 11 3354 3081

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