

Combination of citalopram and nortriptyline in the treatment of moderate to severe major depression: a double-blind placebo-controlled trial

Submission date 08/06/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/06/2005	Overall study status Completed	☐ Protocol
Last Edited 06/11/2009	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

110

Study information

Scientific Title

Acronym

Depression Project

Study objectives

Depression is one of the most common psychiatric disorders, which can be categorized as mild to severe. Combination therapy may rapidly reduce depressive symptoms in patients with moderate to severe depression and is more effective than monotherapy, but it is controversial. In fact, serotonergic and noradrenergic enhancement may be synergistic and more effective than serotonergic enhancement alone in treating depression. The object of this double-blind study was to compare the efficacy and safety of selective serotonin reuptake inhibitor (SSRI)-tricyclic antidepressant (TCA) combination with SSRI alone in patients with moderate to severe depression.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

All patients gave a complete medical and psychiatric history and were given a physical examination before entry into the study. Then 19 subjects were assigned in a random fashion to nortriptyline 50 mg/day plus citalopram 40 mg/day (group 1) and 19 subjects to placebo plus citalopram 40 mg/day (group 2) for an 8 week, double-blind, placebo-controlled study. The dosage of citalopram (in both groups) was titrated up to 40 mg/day over three days and the dosage of nortriptyline (in group 1) was titrated up to 50 mg/day over three days. Patients didn't receive other psychopharmacological drugs during the trial and they were not permitted to have psychotherapy. At each scheduled visit, patients were assessed by a resident of psychiatry, using a standardized protocol for the HAM-D at baseline and after 2, 4, 6 and 8 weeks after medication was started.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Citalopram and nortriptyline

Primary outcome(s)

The principal measure of the outcome was the 17-item HAM-D. The mean decrease in HAM-D score from baseline was used as the main outcome measure of response of depression to treatment.

Key secondary outcome(s)

Side-effects were systematically recorded throughout the study and were assessed using a checklist administered by a resident of psychiatry on week 2, 4, 6 and 8.

Completion date

01/01/2005

Eligibility

Key inclusion criteria

After giving informed consent and discontinuing all psychotropic medications for 2 weeks, 45 outpatients (28 female and 17 male) between 18 and 54 years of age were enrolled in the study. Seven subjects dropped out after the first week of treatment due to noncompliance (3 subjects from group 1 and 4 subjects from group 2) leaving 38 patients (24 female and 14 male) who completed the trial. All subjects met the Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) criteria for major depressive disorder (MDD), based on the structured clinical interview for DSM-IV and had a baseline Hamilton Rating scale for depression (HAM-D, 17 item) score of at least 20. The HAM-D is, the most widely used physician-administrated rating scale for depression, summates 17 individual item scores to provide a total score indicative of the severity of depression.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Patients with a history of other psychiatric disorders, history of bipolar disorder, personality disorder, anxiety disorder, substance abuse, alcoholism, and organic brain disorders were excluded. Also patients were excluded if they were psychotic or posed a significant risk of

suicide at any time during participation. Pregnant or lactating women were excluded. All patients were free of unstable medical disorders including cardiovascular, hepatic, renal, gastrointestinal, pulmonary, metabolic, endocrine or hematological illnesses.

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

Iran

Study participating centre

Roozbeh Psychiatric Hospital

Tehran

Iran

13185

Sponsor information

Organisation

Tehran University of Medical Sciences (Iran)

ROR

<https://ror.org/01c4pz451>

Funder(s)

Funder type

University/education

Funder Name

Tehran University of Medical Sciences (Iran) (ref: 110)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration