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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2003

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

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
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Sponsor information

Organisation
Tehran University of Medical Sciences (Iran)

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Sponsor type
University/education

ROR
https://ror.org/01c4pz451

Funder(s)

Funder type
University/education

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration