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Combination of pharmacotherapy with electroconvulsive therapy in prevention of relapse in major depressive disorder: a randomised, placebo controlled, double-blind study

Submission date	Recruitment status
28/03/2008	No longer recruiting
Registration date	**Overall study status**
09/05/2008	Completed
Last Edited	**Condition category**
13/04/2021	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
AY0022

Study information

Scientific Title
A new strategy of continuation pharmacotherapy in the prevention of relapse following electroconvulsive therapy: a controlled trial

Study objectives
1. The frequency of relapse of depressive symptoms will be lower in the group with concomitant antidepressant treatment after the 4th electroconvulsive therapy (ECT) compared to the group taking placebo.
2. The frequency of relapse of depressive symptoms will be lower in the group with concomitant antidepressant treatment after the 4th ECT compared to the group taking antidepressant treatment after the 8th ECT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Dokuz Eylul University Institutional Review Board, Izmir, Turkey on 03/10/2002 (version 0.0). Amendments were approved on the following dates:
Version 0.1: 16/07/2003
Version 0.2: 03/10/2004

Study design
Randomised, double-blind, placebo-controlled, parallel-arms 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
Major depressive disorder

Interventions
Consented subjects who met the inclusion and exclusion criteria were consulted by an anesthesian and cardiologist before starting ECT. Each subject received 8 effective bilateral ECT at a frequency of twice a week.

After completion of 4th ECT session, the participants were randomly allocated to the following three arms:

1. C-Pharm Early
2. C-Pharm Late
3. C-Pharm Placebo

Randomisation to C-Pharm Early: C-Pharm Late: C-Pharm Placebo groups was 2:2:1.

On the day of randomisation C-Pharm Early group was given sertraline hydrochloride (150 mg /day); C-Pharm Late group was first given identical placebo tablets, which was then substituted with sertraline hydrochloride (150 mg/day) after the completion of the 8th ECT. C-Pharm Placebo group was administered identical placebo tablets throughout the interventions.

Participants were evaluated weekly during the first 4 weeks, then biweekly by Montgomery-Asberg Depression Rating Scale (MADRS) throughout the study period. After the completion of the 8 ECTs, remitters in each study group were identified. To be defined as remitted, patients had to achieve a maximum score of 12 in MADRS.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
sertraline hydrochloride

Primary outcome measure
Rate of relapse. The criterion for relapse was a mean MADRS score of at least 16 that is maintained over 2 consecutive visits.

Secondary outcome measures
Estimated mean time to relapse.

Overall study start date
05/04/2004

Completion date
01/02/2007

Eligibility

Key inclusion criteria
1. Be at least 18 years old, male and female
2. Diagnosis of major depressive disorder on the structural clinical interview for the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV)
3. Montgomery-Asberg Depression Rating Scale >22 at screening
4. Providing informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Currently pregnant, planning to become pregnant, or breast feeding
2. History of bipolar disorder, schizophrenia, schizoaffective disorder, nonmood disorder psychosis, neurological illness
3. History of ECT within the past 6 months
4. Drug screen positive for any drug of abuse at screening, active substance abuse in the past 2 weeks or substance dependence in the past 2 months (except nicotine and caffeine)
5. Severe medical illness that markedly increases the risks of ECT (e.g. unstable or severe cardiovascular conditions, aneurysm or vascular malformation susceptible to rupture, severe chronic obstructive pulmonary disease)

Date of first enrolment
05/04/2004

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
Türkiye

Study participating centre
Seferihisar Cad No.6
Izmir
Türkiye
35310

Sponsor information

Organisation
Individual sponsor (Turkey)

Sponsor details
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Sponsor type
Other

Funder(s)

Funder type
Industry

Funder Name
Investigator award from the Pfizer Pharmaceuticals (USA)

Funder Name
Dokuz Eylul University (Turkey)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2010	13/04/2021	Yes	No