

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

<b>Submission date</b> 28/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/04/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 anesthesiologist 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?
<a href="#">Results article</a>		01/06/2010	13/04/2021	Yes	No