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Pharmacological treatment of Depression: Phase II Lithium addition

Submission date	Recruitment status	[ ] Prospectively registered
28/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/04/2006	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

Contact name
Dr W.W. Broek, van den

Contact details
Erasmus Medical Center
Department of Psychiatry
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
w.w.vandenbroek@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The two strategies (Venlafaxine and subsequent Lithium addition in non-responders to Venlafaxine; Imipramine and subsequent Lithium addition in non-responders to Imipramine) are comparable in efficacy and time to response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
A double blind, randomized single-centre study with a washout period, comparing 2 treatment strategies.

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
Venlafaxine (maximum dose 375 mg) and subsequent Lithium addition;
Imipramine (dose adjustment to adequate plasma levels of 200-300 µg/l) and subsequent Lithium addition.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Venlafaxine, Lithium, Imipramine

Primary outcome measure
1. Change in HRSD scores
2. Change in CGI scores

Secondary outcome measures
Adverse effects.

Overall study start date
01/06/2005

Completion date
01/06/2009

Eligibility

Key inclusion criteria
All non-responders in phase I.
In phase I inclusion criteria were:
1. Age 18-65
2. Major depressive disorder, single or recurrent episode (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV])
3. Hamilton Rating Scale for Depression (HRSD) (17 item) greater than or equal to 14
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
69

Key exclusion criteria
Any of the following is regarded as a criterion for exclusion from the trial:
1. Patients who are incapable of understanding the information and of giving informed consent. Also, patients who are unable to read or write
2. Major depression with psychotic features (separate study)
3. Bipolar I or II disorder
4. Schizophrenia or other primary psychotic disorder
5. Treatment of current episode with adequate trial of Imipramine or Venlafaxine

6. Drug/alcohol dependence in the last 3 months
7. Mental retardation (IQ <80)
8. Women: pregnancy or possibility for pregnancy and no adequate contraceptive measures. Breastfeeding.
9. Serious medical illness affecting central nervous system (CNS) e.g. M. Parkinson, systemic lupus erythematosus (SLE), brain tumor, cerebrovascular accident (CVA)
10. Relevant medical illness as contra-indications for the use of study medication (Venlafaxine and Imipramine), such as recent myocardial infarction and severe liver or kidney failure
11. Medication affecting CNS e.g. antidepressants and/or antipsychotics other than study medication, steroids (prednison), mood stabilisers, benzodiazepines (if not being tapered): >3 mg lorazepam (or equivalent)
12. Direct electroconvulsive therapy (ECT) indication (e.g. very severely suicidal or refusal of food and drinking resulting in life threatening situation)
13. Contra-indications for Lithium (Moleman, 1998):
a. Kidney failure
b. Acute myocardial infarction
c. Myasthenia gravis
d. Breastfeeding

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Wyeth

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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