Pharmacological treatment of Depression: Phase II Lithium addition.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25557

Source
NTR

Brief title
N/A

Health condition

A double-blind, and randomized singlecenter trial comparing two treatment strategies in patients with a major depression. During phase I patients were treated during 7 weeks with: Imipramine or Venlafaxine. In phase II the non-responders of phase I will be treated with Lithium addition in an open trial during 4 weeks. During these 4 weeks the antidepressant drugs from phase I will be continued at the same dose under maintaining double-blind conditions.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Unconditional grant from Wyeth the manufacturer of venlafaxine

Intervention

Outcome measures

Primary outcome

1. Change in HRSD scores;
2. Change in CGI scores.

Secondary outcome

Adverse effects.

Study description

Background summary

TITLE
Pharmacological treatment of Depression: Phase II Lithium addition

OBJECTIVES
PRIMARY:
To compare in inpatients with a depression the antidepressive efficacy at 11 weeks of two treatment arms: (1) 7 weeks Venlafaxine (maximum dose 375 mg) and subsequent 4 weeks Lithium addition in the non-responders to Venlafaxine; (2) 7 weeks Imipramine (dose adjustment to adequate plasma levels of 200-300 mug/day) and subsequent 4 weeks Lithium addition in the non-responders to Imipramine.
SECONDARY:
To compare in patients with a depression the tolerability of Lithium
Evaluate efficacy and tolerability during continuation of 4 months of treatment in the responders

TYPE OF PATIENTS:
Non-responders to the treatment of phase I

NUMBER OF PATIENTS:
The expectation is that 50 % will respond in phase I, the 50 % non-responders will be included in phase II. The study starts with 138 patients; thus we expect 69 patients can be included in phase II.

TRIAL DESIGN:
An open addition of Lithium to non-responders of phase I: patients with a depression who were randomized and received double-blind Imipramine or Venlafaxine.

TRIAL TREATMENTS:
1. Venlafaxine (maximum dose 375 mg) and subsequent Lithium addition
2. Imipramine (dose adjustment to adequate plasma levels of 200-300 mug/l) and subsequent Lithium addition

DURATION OF TREATMENT:
4 weeks, with al least 3 weeks lithium with adequate plasma levels

FOLLOW-UP:
Continuation treatment of responders during 4 months

PRIMARY ENDPOINTS:
Proportion of responders
Change in:
1. HRSD scores
2. CGI scores.
SECONDARY ENDPOINTS:
Adverse effects.

Study objective

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

All non-responders in phase I In phase 1 inclusion criteria were:
1. Age 18-65;
2. Major depressive disorder, single or recurrent episode (DSM-IV);
3. HRSD (17 item) larger than or equal to 14;
4. Written informed consent.

Exclusion criteria

1. Patients whom are incapable to understand the information and to give informed consent. And patients whom 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 last 3 months;
7. Mental retardation (IQ smaller than 80);
8. Women: pregnancy or possibility for pregnancy and no adequate contraceptive measures. Breastfeeding;
9. Serious medical illness affecting CNS, e.g.: M. Parkinson, SLE, brain tumor, 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: see appendix ‘Moleman P. 1998. Praktische psychofarmacologie. Derde druk. Bohn Stafleu Van Loghum. Page 19’);
12. Direct 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 myocard infarct;
c. Myasthenia gravis;
d. Breastfeeding.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2005
Enrollment:	69
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL577
NTR-old	NTR633
Other	: N/A
ISRCTN	ISRCTN75768415

Study results

Summary results
N/A