Pharmacological treatment of Depression: Phase II Lithium addition.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25557

Bron
NTR

Verkorte titel
N/A

Aandoening

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.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Unconditional grant from Wyeth the manufacturer of venlafaxine

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2005
Aantal proefpersonen:	69
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A