Pharmacological Treatment of Depression.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22391

Source
NTR

Brief title
Venla study

Health condition

This is a double blind, randomized study with a washout period, comparing 2 treatments strategies.
Study duration is 1 week washout period, 7 weeks acute treatment and continuation treatment of responders during 4 months.

One condition is with imipramine with adequate plasma levels the other is venlafaxine with optimal dosage

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Wyeth

Intervention

Outcome measures

Primary outcome

Change in HRSD scores.

Secondary outcome

1. Change in CGI scores;

2. Response defined as > 50% reduction on HRSD compared to baseline;

3. Remission defined as an end score of < 7 on the HRSD.

Study description

Background summary

TITLE:

Pharmacological treatment of Depression: Phase I Venlafaxine versus Imipramine

OBJECTIVES:

Primary:

1. To compare in inpatients with a depression the antidepressant efficacy at seven weeks of two treatment arms: (1) 7 weeks Venlafaxine (maximum dose 375 mg); (2) 7 weeks Imipramine (dose adjustment to adequate plasma levels of 200-300 mug/day).

Secondary:

1. To compare in patients with a depression the tolerability of Venlafaxine and Imipramine;

2. Evaluate efficacy and tolerability during continuation of 4 months of treatment in the responders;

3. Measure plasma level of Venlafaxine:
Patients with Venlafaxine plasma levels under 195 µg/L (not a therapeutical range) show lesser improvement in HRSD/ CGI scores.

TYPE OF PATIENTS:

Inpatients of the Erasmus MC with a severe major depression.

NUMBER OF PATIENTS:

138.

TRIAL DESIGN:

A double blind, randomized singlecentre study with a washout period, comparing 2 treatment strategies.

TRIAL TREATMENTS:

1. Venlafaxine (maximum dose 375 mg);

2. Imipramine (dose adjustment to adequate plasma levels of 200-300 µg/l).

DURATION OF TREATMENT:

One week washout and 7 weeks acute treatment with Venlafaxine or Imipramine. Total of 8 weeks;

FOLLOW-UP:

Continuation treatment of responders during 4 months.

PRIMARY ENDPOINTS:

Proportion of responders.

Change in:

1. HRSD scores;

2. CGI scores;

3. Time to response;

4. Adverse effects.

Study objective

1. Imipramine and Venlafaxine are comparable in efficacy in inpatients with a major depression;

2. Imipramine and Venlafaxine are comparable in tolerability;

3. Patients with a Venlafaxine plasma level < 195 µg/L show comparable antidepressant efficacy as patients with a Venlafaxine plasma level > 195 µg/L;

4. Imipramine and Venlafaxine are comparable in efficacy during 4 months follow-up;

5. Imipramine and Venlafaxine are comparable in tolerability during 4 months follow-up.

Intervention

1. Venlafaxine (maximum dose 375 mg);

2. Imipramine (dose adjustment to adequate plasma levels of 200-300 µg/l).

Contacts

Public
Erasmus Medical Center, Department of Psychiatry,
P.O. Box 2040
W.W. Broek, van den
Rotterdam 3000 CA
The Netherlands
Scientific
Erasmus Medical Center, Department of Psychiatry,
P.O. Box 2040
W.W. Broek, van den
Rotterdam 3000 CA
The Netherlands

Eligibility criteria

Inclusion criteria

For inclusion in the trial, patients must fulfill all of the following criteria:

1. Age 18-65;

2. Major depressive disorder, single or recurrent episode (DSM-IV);

3. HRSD (17 item) >= 14;

4. Written informed consent.

Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the trial:

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 < 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
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2004
Enrollment:	138
Type:	Actual

Ethics review

Positive opinion

Date:	08-03-2006
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	NL563
NTR-old	NTR619
Other	: N/A
ISRCTN	ISRCTN73221288

Study results

Summary results
N/A