Pharmacological Treatment of Depression.

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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...

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

Samenvatting

ID

NL-OMON22391

Bron
NTR

Verkorte titel
Venla study

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Wyeth

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in HRSD scores.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

1. Venlafaxine (maximum dose 375 mg);

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

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2004
Aantal proefpersonen:	138
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-03-2006

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	NL563
NTR-old	NTR619
Ander register	: N/A
ISRCTN	ISRCTN73221288

Resultaten

Samenvatting resultaten
N/A