Pharmacological treatment of psychotic depression.

Gepubliceerd: 23-12-2004 Laatst bijgewerkt: 18-08-2022

Primary: 1. To compare in inpatients with psychotic depression the antidepressive efficacy at seven weeks of three treatment arms: [1] 7 weeks venlafaxine (maximum dose 375 mg); [2] 7 weeks imipramine (dose adjustment to adequate plasma levels...

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

Samenvatting

ID

NL-OMON24572

Bron
NTR

Verkorte titel
DUDG (Dutch University Depression Group)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of responders.

Toelichting onderzoek

Achtergrond van het onderzoek

Title:

Pharmacological Treatment of Psychotic Depression.

Objectives:

Primary:

1. To compare in inpatients with psychotic depression the antidepressive efficacy at seven weeks of three treatment arms: [1] 7 weeks venlafaxine (maximum dose 375 mg); [2] 7 weeks imipramine (dose adjustment to adequate plasma levels of 200 ? 300 ug/L); [3] 7 weeks venlafaxine (maximum dose 375 mg) plus quetiapine (max. 600 mg/day).

Secondary:

1. To compare in patients with psychotic depression the tolerability of venlafaxine, imipramine and venlafaxine plus quetiapine.

2. To find factors modifying treatment efficacy, such as response to earlier treatments during current episode.

3. To evaluate efficacy and tolerability of continuation treatment during 4 months in responders to treatment at 7 weeks.

Type of patients:

In-patients with psychotic depression.

Number of patients:

To include 180 patients (3 groups of 60 patients) 250 patients must be selected in 6 centres.

Trial design:

A double blind, randomised and stratified to the centres, multicentre study with a wash-out period, comparing 3 treatment strategies.

Trial treatments:

1. Venlafaxine (maximum dose 375 mg);

2. Imipramine (dose adjustment to adequate plasma levels of 200 ? 300 ug/L);

3. Venlafaxine (maximum dose 375 mg) plus quetiapine (max. 600 mg/day).

Duration of treatment:

One week wash-out and 7 weeks acute treatment with venlafaxine or imipramine or venlafaxine plus quetiapine. Total: 8 weeks.

Follow-up:

Continuation treatment of responders during 4 months.

Primary endpoints:

1. Proportion of responders.

Secondary endpoints:

1a. Change in HRSD scores;

1b. Change in CGI scores;

2. Time to response;

3. Adverse effects;

4. Group differences especially with regard to response to earlier treatments during current episode.

Doel van het onderzoek

Primary:

1. To compare in inpatients with psychotic depression the antidepressive efficacy at seven weeks of three treatment arms:
[1] 7 weeks venlafaxine (maximum dose 375 mg);

[2] 7 weeks imipramine (dose adjustment to adequate plasma levels of 200 ? 300 ug/L);

[3] 7 weeks venlafaxine (maximum dose 375 mg) plus quetiapine (max. 600 mg/day);

Secondary:

1. To compare in patients with psychotic depression the tolerability of venlafaxine, imipramine and venlafaxine plus quetiapine;

2. To find factors modifying treatment efficacy, such as response to earlier treatments during current episode;

3. To evaluate efficacy and tolerability of continuation treatment during 4 months in responders to treatment at 7 weeks.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Trial treatments:

1 Venlafaxine (maximum dose 375 mg).

2. Imipramine (dose adjustment to adequate plasma levels of 200 – 300 ug/L).

3. Venlafaxine (maximum dose 375 mg) plus quetiapine (max. 600 mg/day).

Duration of treatment:

One week wash-out and 7 weeks acute treatment with venlafaxine or imipramine or venlafaxine plus quetiapine. Total: 8 weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-65;

2. Major depressive disorder, single or recurrent episode, with psychotic features (Diagnostic and Statistical Manual of Mental Disorders, Fourth edition [DSM IV]);

3. Hamilton Rating Scale for Depression (HRSD) (17 item) 18;

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Bipolar I or II disorder;

2. Schizophrenia or other primary psychotic disorder;

3. Treatment of current episode with adequate trial of imipramine or venlafaxine.

- imipramine at least 4 weeks with adequate bloodlevels;

- venlafaxine at least 4 weeks ? 300 mg dd;

4. Drug/alcohol dependence last 3 months;

5. Mental retardation (IQ <80);

6. Women: pregnancy or possibility for pregnancy and no adequate contraceptive measures. Breast-feeding;

7. Serious medical illness affecting CNS, e.g: M Parkinson, SLE, brain tumor, CVA;

8. Relevant medical illness as contra-indications for the use of study medication, such as recent myocardial infarction;

9. Medication affecting CNS, e.g:

antidepressives and/or antipsychotics other than study medication, steroids (prednison), mood stabilizers, 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’);

10. Direct ECT indication (e.g. very severe suicidality or refusal of food and drinking resulting in a life threatening situation);

11. MAO-I < 1 week before start of medication free period.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2002
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-12-2004
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	NL11
NTR-old	NTR26
Ander register	: N/A
ISRCTN	ISRCTN36607067

Resultaten

Samenvatting resultaten
N/A