Pharmacological treatment of psychotic depression.

No registrations found.

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

Summary

ID

NL-OMON24572

Source
NTR

Brief title
DUDG (Dutch University Depression Group)

Intervention

Outcome measures

Primary outcome

Proportion of responders.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	01-03-2002
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	23-12-2004
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	NL11
NTR-old	NTR26
Other	: N/A
ISRCTN	ISRCTN36607067

Study results

Summary results
N/A