A randomised, double-blind, parallel-group comparison of the efficacy and the safety of venlafaxine versus nortriptyline in the treatment of depressed elderly inpatients.

No registrations found.

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

Summary

ID

NL-OMON27258

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

Remission on the MADRS (final score of 10 or less).

Secondary outcome

Remission on HAM-D and GDS, response on MADRS, HAM-D and GDS, number of side effects, Global Tolerability Score, MMSE, Barthel ADL score, SF-20.

Study description

Background summary

Most trials on pharmacological treatment of major depression in the elderly are outpatient trials, which mostly included relatively young, physically healthy, moderate depressed patients. As a result of this, data are lacking on the treatment of the most severe and difficult-to-treat forms of depression in the elderly. In this 'real- world' trial, depressed inpatients with moderate-severe depression and, most often many physicall illnesses, are included and treated with either venlafaxine or nortriptyline.

Study objective

Venlafaxine and nortriptyline are not significant different in efficacy in elderly inpatients with depression but venlafaxine is better tolerated.

Study design

N/A

Intervention

Nortriptyline (range 25-200 mg) or venlafaxine (range 75-300 mg).

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Eligibility criteria

Inclusion criteria

1. Male or female inpatient;

2. Aged 60 years or older;

3. Meet the DSM-IV criteria for major depression, single or recurrent episode (296.2x, 296.3x), dysthymic disorder (300.4), mood disorder due to a general medical condition, with depressive features or with major depressive -like episode (293.83), substance induced mood disorder with depressive features (292.84), depressive disorder not otherwise specified (i.e. minor depressive disorder) (311);

4. Have a baseline MADRS total score ? 20;

5. Have a baseline MMSE score > 15;

6. Written informed consent.

Exclusion criteria

1. Known hypersensivity to venlafaxine or nortriptyline;

2. Previous unsuccessful treatment with venlafaxine for at least 4 weeks with a minimum dose of 75 mg/day or previous unsuccessful treatment with nortriptyline for at least 4 weeks with a serum level within the therapeutic range;

3. Relevant medical illness which is a contra-indication for the use of the study medication, such as myocardial infarction within previous 6 months;

4. Use of electroconvulsive therapy (ECT) within 30 days prior to baseline, use of a MAO inhibitor within 14 days, use of fluoxetine within 21 days, use of any antidepressant drug (except those allowed during the study as concomitant treatment) within 3 days prior to baseline;

5. Alcohol or drug abuse within the last year, according to DSM IV criteria;

6. Presence of dementia, or a non-affective psychotic disorder, or a history of bipolar disorder (I and II), all according to DSM-IV criteria.

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):	01-10-1999
Enrollment:	81
Type:	Actual

Ethics review

Positive opinion

Date:	26-01-2005
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	NL3
NTR-old	NTR27
Other	: N/A
ISRCTN	ISRCTN23246262

Study results

Summary results

1. Int J Geriatr Psychiatry. 2007 Dec;22(12):1247-54.
