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

Gepubliceerd: 26-01-2005 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON27258

Bron
Nationaal Trial Register

Verkorte titel
N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-1999
Aantal proefpersonen:	81
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-01-2005
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	NL3
NTR-old	NTR27
Ander register	: N/A
ISRCTN	ISRCTN23246262

Resultaten

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