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

Submission date
16/05/2005

Recruitment status
No longer recruiting

Registration date
16/05/2005

Overall study status
Completed

Last Edited
02/04/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR27

Study information

Scientific Title

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, double blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Depressive disorders

Interventions
1. Nortriptyline (range 25 - 200 mg)
2. Venlafaxine (range 75 - 300 mg)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Venlafaxine, nortriptyline

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

Secondary outcome measures
1. Remission on Hamilton Depression rating scale (HAM-D) and Geriatric Depression Scale (GDS)
2. Response on MADRS, HAM-D and GDS
3. Number of side effects
4. Global Tolerability Score
5. MMSE
6. Barthel Activities of Daily Living (ADL) score
7. 20-item Short Form health survey (SF-20)

Overall study start date
01/10/1999

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. Male or female inpatient
2. Aged 60 years or older
3. Meet the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for:
3.1. Major depression, single or recurrent episode (296.2x, 296.3x)
3.2. Dysthymic disorder (300.4)
3.3. Mood disorder due to a general medical condition, with depressive features or with major depressive-like episode (293.83)
3.4. Substance induced mood disorder with depressive features (292.84)
3.5. Depressive disorder not otherwise specified (i.e. minor depressive disorder) (311)
4. Have a baseline Montgomery-Asberg Depression Rating Scale (MADRS) total score greater than or equal to 20
5. Have a baseline Mini-Mental State Examination (MMSE) score greater than 15
6. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
81

Key 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 monoamine oxidase (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

Date of first enrolment
01/10/1999

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Altrecht GGZ
Utrecht
Netherlands
3522 HR

Sponsor information

Organisation
Altrecht GGZ (The Netherlands)

Sponsor details
Jutfaseweg 205
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Sponsor type
Industry

Website
http://www.altrecht.nl/

ROR
https://ror.org/050jqep38

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceuticals B.V. (The Netherlands) (ref: 100186)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/12/2007		Yes	No