Treatment-resistent depression in the elderly.

No registrations found.

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

Summary

ID

NL-OMON28173

Source
NTR

Brief title
N/A

Health condition

Major depression.

Sponsors and support

Primary sponsor: ZON-MW
Source(s) of monetary or material Support: Parke-Davis

Intervention

Outcome measures

Primary outcome

Efficacy: remission defined as a final score of 10 or less on the MADRS.

Tolerability: Global Tolerability Score.

Secondary outcome

Response defined as a reduction of at least 50 % of MADRS, HAM-D and GDS, CGI 1-2. Remission on HAM-D, GDS. Number of (serious) side effects and drop out rate due to the study medication. MMSE-score, TMT, VLGT (cognitive tests).

Study description

Background summary

A minority of 20-40% of elderly depressed patients fails to respond to pharmacological treatment. These patients may be treated in a number of different ways, but randomised controlled trials in the elderly are not available. Two often used strategies in treatment-resistant depressed elderly in the Netherlands are augmentation with lithium and an irreversible MAO inhibitor. Both will be compared in a randomised, single-blind study design.

Study objective

Both active medications are equally effective in the treatment of non-responding elderly patients but phenelzine is better tolerated than lithium.

Study design

N/A

Intervention

Patients start with either phenelzine 15 mg or lithiumcabonate 200 mg. The dose will be increased with phenelzine 15 mg or lithiumcarbonate 200 mg after 4-8 days.
The minimum daily dose of phenelzine is 15 mg and the maximum daily dose is 60 mg.
Lithium is dosed to reach a serum level between 0.6 - 0.8 mmol/l.

Contacts

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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);

4. Non-response to adequate treatment with a tricyclic antidepressant (minimal 4-6 weeks with serum levels within therapeutic window) or venlafaxine (minimal 4-6 weeks with a sum serum level of venlafaxine+ O-desmethylvenlafaxine > 200 microgram);

5. Have a baseline total score of at least 20 on the MADRS;

6. Have a MMSE score > 15;

7. In the opinion of the investigator, have sufficient intelligence and motivation to comply with, and is competent to understand, the study procedures (especially dietary instructions in case of phenelzine);

8. Sign the written informed consent.

Exclusion criteria

1. Known hypersensitivity to lithium or phenelzine;

2. Previous unsuccessful adequate (minimal 15 mg during 4 weeks) treatment with phenelzine or with lithiumaugmentation (minimal serum level of 0.6 mmol/l during 4 weeks);

3. Use of lithium or phenelzine within 30 days prior to baseline, use of a MAO inhibitor within 14 days, use of fluoxetine within 21 days, use of any other psychotropic drug (except

antidepressants and those allowed during the study as concomitant treatment) within 7 days prior to baseline;

4. The presence of a physical illness which serious interacts with treatment with either lithium or phenelzine;

5. Alcohol or drug abuse within the last 2 years, according to DSM IV criteria;

6. Presence of dementia or non-affective psychotic disorder, history of bipolar disorder (I and II);

7. Concomitant use of alcohol or drugs that can have serious interactions with phenelzine or lithium.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2000
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	13-10-2005
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	NL413
NTR-old	NTR453
Other	: 1360.0001
ISRCTN	ISRCTN93105957

Study results

Summary results

1. J Clin Psychiatry. 2007 Aug;68(8):1177-85.