Treatment-resistent depression in the elderly.

Gepubliceerd: 13-10-2005 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON28173

Bron
NTR

Verkorte titel
N/A

Aandoening

Major depression.

Ondersteuning

Primaire sponsor: ZON-MW
Overige ondersteuning: Parke-Davis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

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);

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2000
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-10-2005
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	NL413
NTR-old	NTR453
Ander register	: 1360.0001
ISRCTN	ISRCTN93105957

Resultaten

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