

Treatment-resistant depression in the elderly

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/08/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rob M. Kok

Contact details
Altrecht GGZ
Jutfaseweg 205
Utrecht
Netherlands
3522 HR
+31 (0)30 2297600
r.kok@altrecht.nl

Additional identifiers

Protocol serial number
NTR453; 1360.0001

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised single blind active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

Patients start with either phenelzine 15 mg or lithiumcarbonate 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.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Phenelzine, lithiumcarbonate

Primary outcome(s)

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

Tolerability: Global Tolerability Score.

Key secondary outcome(s)

1. Response defined as a reduction of at least 50% of MADRS, Hamilton Depression Scale (HAM-D) and Geriatric Depression Scale (GDS), Clinical Global Impression (CGI) 1-2
2. Remission on HAM-D, GDS
3. Number of (serious) side effects and drop out rate due to the study medication
4. MMSE-score, Trail Making Test (TMT), Dutch Verbal Learning and Memory Test (Verbale Leer en Geheugen Test [VLGT]) (cognitive tests)

Completion date

01/01/2005

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 (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 Montgomery-Asberg Depression Rating Scale (MADRS)
6. Have a Mini Mental State Examination (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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Known hypersensitivity to lithium or phenelzine
2. Previous unsuccessful adequate (minimal 15 mg during 4 weeks) treatment with phenelzine or with lithium augmentation (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 MonoAmine Oxide (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 seriously 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

Date of first enrolment

01/01/2000

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Altrecht GGZ

Utrecht

Netherlands

3522 HR

Sponsor information

Organisation

Altrecht Mental Health Care (Altrecht Geestelijke Gezondheidszorg [GGZ]) (Netherlands)

ROR

<https://ror.org/050jqep38>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Parke Davis (USA)

Alternative Name(s)

Parke Davis & Company

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

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	01/08/2007		Yes	No