# Treatment-resistant depression in the elderly

[ ] Prospectively registered Submission date Recruitment status 27/01/2006 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 27/01/2006 Completed [X] Results [ ] Individual participant data Last Edited Condition category 17/08/2009 Mental and Behavioural Disorders

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Study design

Randomised single blind active controlled parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

#### Study type(s)

**Treatment** 

#### Participant information sheet

### 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 measure

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

Tolerability: Global Tolerability Score.

#### Secondary outcome measures

- 1. Response defined as a reduction of at least 50% of MADRS, Hamilton Depression Scale (HAMD) 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)

#### Overall study start date

01/01/2000

#### 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

#### Age group

Senior

#### Sex

Both

### Target number of participants

30

#### 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 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 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)

# Sponsor details

Jutfaseweg 205 Utrecht Netherlands 3522 HR

#### Sponsor type

Hospital/treatment centre

#### 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**

#### 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	01/08/2007		Yes	No