ISRCTN93105957 https://doi.org/10.1186/ISRCTN93105957

Treatment-resistant depression in the elderly

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
17/08/2009

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
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 (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)

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