THE EFFICACY OF PAROXETINE AND COGNITIVE-BEHAVIOURAL THERAPY IN THE TREATMENT OF LATE-LIFE PANIC DISORDER: A RANDOMIZED CONTROLLED TRIAL.

No registrations found.

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

Summary

ID

NL-OMON23124

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Panic disorder;

2. aged;

3. drug therapy;

4. cognitive therapy;

5. paroxetine.

(NLD: Paniekstoornis, ouderen, farmacotherapie, cognitieve gedragstherapie, paroxetine).

Sponsors and support

Primary sponsor: 1. Radboud University Nijmegen, Behavioural Science Institute, Nijmegen, the Netherlands: Prof. dr. C.A.L. Hoogduin, Dr. G.P.J. Keijsers;
2. GGz Nijmegen, Outpatient Department for Anxiety Disorders, Nijmegen
PO Box 7049, 6503 GM Nijmegen, the Netherlands.
Source(s) of monetary or material Support: Unrestricted grant:
Glaxo SmithKline BV, PO Box 780, 3700 AT Zeist, the Netherlands.

Intervention

Outcome measures

Primary outcome

Self-report instruments for anxiety cogntions and phobic avoidance: scores on the Dutch adaptations of the Agoraphobic Cognitions Questionnaire (ACQ) and the Mobility Inventory avoidance scale (MI).

Secondary outcome

Self-report instruments for depression and general psychopathology. Depressive symptoms were assessed with the Dutch adaptation of the Beck Depression Inventory (BDI) and general psychopathology was assessed with the Dutch adaptation of the Symptom Checklist (SCL-90).

Study description

Background summary

N/A

Study objective

1. Both paroxetine and cognitive behavioural therapy (CBT) are effective in the treatment of late-life panic disorder;

2. Differences in efficacy between paroxetine and CBT are small.

Study design

Assessments were completed at:

1. Week 0;

2. Week 8;

3. Week 14;

4. Week 26.

Intervention

1. Treatment with paroxetine 20 mg 1dd2 during 14 weeks;

2. Cognitive behavioural therapy according to a treatment manual for panic disorder during 14 weekly sessions;

3. A waiting-list control condition of 14 weeks.

For both active treatments, paroxetine and CBT, follow-up period is 12 weeks.

Contacts

Public
GGz Nijmegen, Outpatient Department for Anxiety Disorders, Nijmegen
PO Box 7049,
G.J. Hendriks
Nijmegen 6503 GM
The Netherlands
+31-24-3837820
Scientific
GGz Nijmegen, Outpatient Department for Anxiety Disorders, Nijmegen
PO Box 7049,
G.J. Hendriks
Nijmegen 6503 GM
The Netherlands
+31-24-3837820

Eligibility criteria

Inclusion criteria

1. Panic disorder with/without agoraphobia (DSM-IV-criteria);

2. >60 years.

Exclusion criteria

1. The presence of severe psychiatric disorders (e.g. psychosis, major depression, bipolar disorder);

2. A severe somatic condition which would hinder appropriate application of CBT (e.g. severe cardiovascular disease);

3. A contraindication for prescribing paroxetine (e.g. co-occurring use of anti-coagulantia);

4. Current use of an antidepressant in an adequate dose;

5. Current and adequate psychological treatment;

6. Abuse or dependency of alcohol or psychoactive substances;

7. Dementia and a score of 23 or less on the Mini-Mental State Examination.

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):	01-01-1999

Enrollment:	80
Type:	Actual

Ethics review

Positive opinion Date:	27-11-2007
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	NL1110
NTR-old	NTR1144
Other	CCMO-Arnhem/Nijmegen : 9803-0063.
ISRCTN	ISRCTN wordt niet aangevraagd/retrospectief

Study results

Summary results
N/A