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Dose Escalation Legitimate? Pharmacology and Imaging studies in depression

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/01/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR193

Study information

Scientific Title
Dose Escalation Legitimate? Pharmacology and Imaging studies in depression

Acronym
DELPHI-trial and DELPHI-SPECT

Study objectives
Dose-escalation of paroxetine (up to 50 mg/day) does not increase efficacy of treatment of major depressive disorder in patients who did not respond to a six week trial of paroxetine in a standard dose (20 mg/day).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, double-blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression, major depressive disorder

Interventions
After six weeks of open treatment with a standard dose of paroxetine (20 mg/day) the patients who have not responded (less than 50% decrease in baseline HDRS-17) will be randomised to receive either a true or a placebo increase (by capsules) in addition to the standard dose.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Paroxetine

Primary outcome(s)
1. Response and remission rates (decrease of greater than or equal to 50% in HDRS-17 and HDRS-17 less than or equal to 7 respectively)
2. Total and specific (due to side-effects or inefficacy) drop-out

Key secondary outcome(s))
1. Occurrence of side-effects (physical and sexual)
2. Subjective well-being and 36-item Medical Outcome Study Short-Form Health Survey (MOS-SF-36) quality of life
3. Direct and indirect costs (TiC-P)

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Major depressive disorder according to Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) (determined by Structured Interview for DSM-IV [SCID-I])
2. 17-item Hamilton Depression Rating Scale (HDRS-17) greater than 18
3. Age 18 to 70 years
4. Maximum of one previous treatment-trial with an antidepressant (of adequate duration [6 weeks] and dosage [maximum recommended dose]) for the current MDD episode

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Bipolar disorder, psychosis or cognitive impairment (dementia or low intelligence quotient [IQ])
2. Use of psychoactive medication (except low doses of benzodiazepines)
3. Previous adequate trial with paroxetine with insufficient response for the current episode
4. Primary alcohol or drugs abuse
5. MDD secondary to co-morbid anxiety or somatophorm disorder
6. Somatic illnesses, e.g. untreated thyroid or other endocrine illnesses, systemic illnesses
7. Pregnancy or wish to become pregnant
8. Severe and acute suicidality
9. Insufficient knowledge of Dutch to fill in questionnaires

Date of first enrolment
01/11/2003

Date of final enrolment
31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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	01/03/2009		Yes	No
Results article	results	01/04/2012		Yes	No
Results article	results	01/02/2015		Yes	No