

Dose Escalation Legitimate? Pharmacology and Imaging studies in depression

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/01/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof A H Schene

Contact details
Academic Medical Centre
Program for Mood Disorders
Department of Psychiatry
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+ 31 (0)20 566 2088
A.H.Schene@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/11/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

500

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)

Sponsor details

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

University/education

Website

<http://www.amc.uva.nl/>

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

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