

Pharmacological treatment of psychotic depression

Submission date 16/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/05/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/04/2008	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
NTR26

Study information

Scientific Title

Acronym

DUDG (Dutch University Depression Group)

Study objectives

Primary hypothesis:

To compare in in-patients with psychotic depression the anti-depressive efficacy at seven weeks of three treatment arms:

1. Seven weeks venlafaxine (maximum dose 375 mg)
2. Seven weeks imipramine (dose adjustment to adequate plasma levels of 200 - 300 µg/l)
3. Seven weeks venlafaxine (maximum dose 375 mg) plus quetiapine (maximum 600 mg/day)

Secondary hypotheses:

1. To compare in patients with psychotic depression the tolerability of venlafaxine, imipramine and venlafaxine plus quetiapine
2. To find factors modifying treatment efficacy, such as response to earlier treatments during current episode
3. To evaluate efficacy and tolerability of continuation treatment during four months in responders to treatment at seven weeks

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, double-blind, active-controlled, parallel, multi-centre 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

In-patients with psychotic depression

Interventions

Trial treatments:

1. Venlafaxine (maximum dose 375 mg)
2. Imipramine (dose adjustment to adequate plasma levels of 200 - 300 µg/l)
3. Venlafaxine (maximum dose 375 mg) plus quetiapine (max 600 mg/day)

Duration of treatment: one week wash-out and seven weeks acute treatment with venlafaxine or imipramine or venlafaxine plus quetiapine. Total: eight weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Venlafaxine, imipramine, quetiapine

Primary outcome measure

Proportion of responders.

Secondary outcome measures

1. Change in:
 - 1.1. HRSD scores
 - 1.2. Clinical Global Impressions (CGI) scale
2. Time to response
3. Adverse effects
4. Group differences, especially with regard to response to earlier treatments during current episode

Overall study start date

01/03/2002

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years
2. Major depressive disorder, single or recurrent episode, with psychotic features (Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV])
3. Hamilton Rating Scale for Depression (HRSD) (17 item)
4. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

Any of the following is regarded as a criterion for exclusion from the trial:

1. Bipolar I or II disorder
2. Schizophrenia or other primary psychotic disorder
3. Treatment of current episode with adequate trial of imipramine or venlafaxine:
 - 3.1. Imipramine at least four weeks with adequate blood levels
 - 3.2. Venlafaxine at least four weeks 300 mg dd
4. Drug/alcohol dependence in the last three months
5. Mental retardation (intelligent quotient [IQ] less than 80)
6. Women:
 - 6.1. Pregnancy or possibility for pregnancy and no adequate contraceptive measures
 - 6.2. Breast-feeding
7. Serious medical illness affecting central nervous system (CNS) e.g. Parkinson's Disease, systemic lupus erythematosus (SLE), brain tumour, cerebrovascular accident (CVA)
8. Relevant medical illness as contra-indications for the use of study medication, such as recent myocardial infarction
9. Medication affecting CNS, e.g. anti-depressives and/or anti-psychotics other than study medication, steroids (prednisone), mood stabilisers, benzodiazepines (if not being tapered): greater than 3 mg lorazepam (or equivalent)
10. Direct electroconvulsive therapy (ECT) indication (e.g. very severe suicidality or refusal of food and drinking resulting in a life threatening situation)
11. Monoamine oxidase inhibitor (MAO-I) less than one week before start of medication free period

Date of first enrolment

01/03/2002

Date of final enrolment

01/07/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Utrecht (UMCU)

Utrecht

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Sponsor information

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details

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Sponsor type

University/education

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals B.V. (The Netherlands)

Funder Name

AstraZeneca (The Netherlands)

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

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