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Pharmacological treatment of psychotic depression

Submission date	Recruitment status	[ ] Prospectively registered
16/05/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/04/2008	Mental and Behavioural Disorders	[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised, double-blind, active-controlled, parallel, multi-centre trial

Study type(s)
Treatment

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(s)
Proportion of responders.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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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3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

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, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary