

Pharmacological treatment of depression

Submission date 28/04/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
N/A

Study information

Scientific Title
Pharmacological treatment of depression

Acronym
Venla study

Study objectives

1. Imipramine and Venlafaxine are comparable in efficacy in inpatients with a major depression
2. Imipramine and Venlafaxine are comparable in tolerability
3. Patients with a Venlafaxine plasma level <195 µg/l show comparable antidepressant efficacy as patients with a Venlafaxine plasma level >195 µg/l
4. Imipramine and Venlafaxine are comparable in efficacy during 4 months follow-up
5. Imipramine and Venlafaxine are comparable in tolerability during 4 months follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Double-blind randomized single-centre study with a washout period comparing 2 treatment strategies

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

1. Venlafaxine (maximum dose 375 mg)
2. Imipramine (dose adjustment to adequate plasma levels of 200-300 µg/l)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Imipramine, Venlafaxine

Primary outcome(s)

Change in HRSD scores.

Key secondary outcome(s)

1. Change in CGI scores
2. Response defined as >50% reduction on HRSD compared to baseline
3. Remission defined as an end score of <7 on the HRSD

Completion date

01/01/2008

Eligibility

Key inclusion criteria

For inclusion in the trial, patients must fulfill all of the following criteria:

1. Age 18-65
2. Major depressive disorder, single or recurrent episode (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV])
3. Hamilton Rating Scale for Depression (HRSD) (17 item) ≥ 14
4. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

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

1. Patients who are incapable of understanding the information and of giving informed consent. Also, patients who are unable to read or write
2. Major depression with psychotic features (separate study)
3. Bipolar I or II disorder
4. Schizophrenia or other primary psychotic disorder
5. Treatment of current episode with adequate trial of Imipramine or Venlafaxine
6. Drug/alcohol dependence in the last 3 months
7. Mental retardation (IQ < 80)
8. Women: pregnancy or possibility for pregnancy and no adequate contraceptive measures. Breastfeeding.
9. Serious medical illness affecting central nervous system (CNS) e.g. M. Parkinson, systemic lupus erythematosus (SLE), brain tumor, cerebrovascular accident (CVA)
10. Relevant medical illness as contra-indications for the use of study medication (Venlafaxine and Imipramine), such as recent myocardial infarction and severe liver or kidney failure
11. Medication affecting CNS e.g. antidepressants and/or antipsychotics other than study medication, steroids (prednisolone), mood stabilisers, benzodiazepines (if not being tapered): > 3 mg lorazepam (or equivalent)
12. Direct electroconvulsive therapy (ECT) indication (e.g. very severely suicidal or refusal of food and drinking resulting in life threatening situation)
13. Contra-indications for Lithium (Moleman, 1998):

- 13.1. Kidney failure
- 13.2. Acute myocardial infarction
- 13.3. Myasthenia gravis
- 13.4. Breastfeeding

Date of first enrolment

01/06/2004

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Industry

Funder Name

Wyeth

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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	01/07/2017		Yes	No