

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Effect of antidepressants on the activity of stress-responsive systems

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Randomized-open, 4-week antidepressant therapy with venlafaxine vs. mirtazapine in patients with unipolar depression as well as 6-month follow-up

Brief Summary in Scientific Language

Randomized-open, 4-week antidepressant therapy with venlafaxine vs. mirtazapine in patients with unipolar depression as well as 6-month follow-up

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000008**
- Date of Registration in DRKS: **2008/09/05**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **0255.6 , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**



Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **Mirtazapin**
- Arm 2: **venlafaxine**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Hamilton Depression Rating Scale:
<8 = remission
-50% = response

Secondary Outcome

[---]*

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2003/04/15**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

major depression (DSM-IV)
Hamilton Depression Rating Scale-21 item version: at least 18

Exclusion criteria

bipolar depression
Depression due to an organic or substance factor
substance dependency
lifetime diagnosis of schizophrenia
glucocorticoid therapy

Addresses

- **Primary Sponsor**
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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

DFG - Deutsche Forschungsgemeinschaft

Kennedyallee 40

53175 Bonn

Germany

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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2007/12/31**

Trial Publications, Results and other documents

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*