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Prospective, randomised evaluation of efficacy of antidepressant monotherapy and antidepressant combinations in the treatment of patients with resistant depression

Submission date 03/09/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/09/2010	**Overall study status** Completed	
Last Edited 27/09/2010	**Condition category** Mental and Behavioural Disorders	

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
IGA MZ CR NS 10368-3

Study information

Scientific Title

Randomised, open-label study comparing the efficacy of antidepressant monotherapy and antidepressant combinations in the acute treatment of patients with resistant depression

Acronym
D-REZ-KOMB

Study objectives
The aim of our study is to examine efficacy of antidepressant monotherapy and combinations of antidepressants in the treatment of resistant depression in common clinical practice. We will test the following null hypotheses:
1. That the reduction of depressive symptoms does not differ between monotherapy and combinations groups
2. The number of responders in both groups does not differ

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of Prague Psychiatric Centre approved on the 21st May 2008

Primary study design
Interventional

Study design
Single centre two arm open label randomised active controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Resistant depressive disorder

Interventions
Patients will be randomly allocated to antidepressant monotherapy group or combination of antidepressant group. Specific antidepressant will be chosen by attending psychiatrist according to clinical judgment and with regard to the history of previous treatment. Antidepressant or combinations of antidepressant will be used in the dose cited in Summary of Products. Both interventions are defined as a new intervention not augmentation of previous antidepressant treatments. We will administer combinations that are commonly used in clinical practice. The total duration of treatment is 6 weeks. We will evaluate stability of outcome in responders after 2 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

The change in the Montgomery-Asberg Depression Rating Scale (MADRS). Patients will be rated at baseline, week 2 week 4 and the end of acute treatment and responders after 2 month of treatment.

Key secondary outcome(s)
Response to treatment that is defined as a greater than or equal to 50% reduction of MADRS score from baseline to the end of treatment.

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Patients suffering from major depressive disorder (recurrent or single episode) diagnosed according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV) criteria, confirmed using the Mini-International Neuropsychiatric Interview (MINI) Czech version 5.0.0.
2. Patients fulfilling at least Stage I criteria for resistant depression according to Thase and Rush, 1997
3. The mental ability to understand and sign Informed Consent Form
4. The score in Montgomery-Asberg Depression Rating Scale greater than or equal to 25 and the score in Clinical Global Impression greater than or equal to 4
5. Outpatients and inpatients
6. Age between 18 and 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Contraindications of used antidepressant treatments according to Summary of product (SPC)
2. The use of antidepressants as a monotherapy or as a part of combination that were ineffective in the treatment of current episode
3. The use of antipsychotics, thymostabilizers and other biological treatment of depression (ECT, rTMS, sleep deprivation etc.) during the study (anxiolytics and hypnotics for case of severe anxiety and insomnia are permitted) as well as formal psychotherapy

4. Comorbidity of Axis I and II (DSM IV) disorders in the 6 month before enrollment to the study
5. Severe or uncontrolled somatic disorders, likely to cause depressive symptoms or interfere with the conduct of the study

Date of first enrolment
01/01/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Czech Republic

Study participating centre
Prague Psychiatric Center
Prague 8-Bohnice
Czech Republic
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Sponsor information

Organisation
Ministry of Health (Czech Republic) - Internal Grant Agency

ROR
https://ror.org/00y6khe77

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Czech Republic) - Internal Grant Agency (ref: No. NS 10368-3)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration