

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

<b>Submission date</b> 03/09/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/09/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**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

**Study design**

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

**Primary study design**

Interventional

**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

181 03

## 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