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The predictors of response to antidepressant treatment in patients with resistant depression- an integrative approach

Submission date
06/06/2013

Recruitment status
No longer recruiting

Registration date
27/06/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a recurrent illness associated with high death rate. Most of the patients do not respond to antidepressants (AD) (drugs used to treat depression/sadness). There is a clear need for methods that select the right treatment for the right patient. Previous studies identified a number of factors associated with successful treatment with antidepressants. Our goal is to compare those factors with standard antidepressants and find out how good these factors are in predicting the outcome of the treatment in patients suffering from depression.

Who can participate?
The study aims to recruit 40 patients with depression (aged between 18-65 years) who failed to respond to at least one antidepressant treatment.

What does the study involve?
Over a period of two years, participants will be invited to take part in the study. It will involve 6-week treatment with standard antidepressants (SSRI) that are usually used. The type of treatment will be decided by a specialist based on the condition of the patient. This will be discussed with the patient as usual. The patient will be invited to give blood sample before start of the new treatment and at week 1 and at the end of study. We will also record the brain activity using electroencephalogram (EEG).

What are the possible benefits and risks of participating?
There will be no immediate direct benefits to those taking part. There will not be considerable risks compared to regular treatment.

Where is the study run from?
The study will be carried out in Prague Psychiatric Center, Czech Republic.

When is the study starting and how long is it expected to run for?
The study starts in May 2013 and its clinical part will finish probably in June 2015. The participation of patients will last for 6 weeks.

Who is funding the study?
This study is funded by Internal Grant Agency of the Ministry of Health, Czech Republic.

Who is the main contact?
Dr Martin Bares
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IGA MZ CR NT 14287

Study information

Scientific Title
The predictors of response to antidepressant treatment in patients with resistant depression-an integrative approach - open-label, prospective study

Study objectives
The aim of our project is to compare efficacy of a decrease of QEEG prefrontal cordance, an increase of brain-derived neurotrophic factor in plasma (pBDNF) and serum brain-derived neurotrophic factor (sBDNF) all after 1st week of treatment, reduction of depressive symptomatology at week 1 and 2 and baseline values of LDAEP in the prediction of response to 6-week treatment with selective serotonin reuptake inhibitors (SSRI) in patients with resistant depression.

The next goal of project is to evaluate predictive ability of combination of above mentioned predictors and to postulate combined predictive model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by Ethic Committee of Prague Psychiatric Center on the 20th June 2012 - reference number 69/12

Study design
Interventional non-randomized single-center open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
More than one previous unsuccessful antidepressant trial lasting 4 or more weeks in the current episode of depression

Interventions
Subjects will be treated with selective serotonin reuptake inhibitors. Specific antidepressant will be chosen by attending psychiatrist according to clinical judgement and with regard to the history of previous treatment. Antidepressants will be used in the dose cited in Summary of Products. The total duration of treatment will be 6 weeks. Concomitant treatment (hypnotics and hydroxyzine) will be used in cases of prominent severe anxiety and insomnia. Depressive symptoms and overall clinical status will be assessed at baseline at week 1, 2, 4 and at the end of study using the MADRS Montgomery-Åsberg Depression Rating Scale, QIDS-SR (Quick Inventory of Depressive symptoms-SR) and CGI (Clinical Global Impression).
EEG (cordance calculations) will be recorded at baseline and after 1week of treatment.
Measurement of BDNF: The blood samples will be collected at baseline, week 1 and at the end of study in patient´s non-fasting state, between 7.00 and 9.00 a.m.
Response to treatment is defined as a reduction of MADRS score higher or equal to 50% at the end of study.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Serotonin reuptake inhibitors

Primary outcome(s)
The ratio of occurrence of a priory defined predictors in responders and non-responders:
1. The reduction of MADRS score ≥20% at week 1 compared to baseline
2. The reduction of MADRS score ≥20% at week 2 compared to baseline
3. Reduction of prefrontal cordance value at week 1 compared to baseline,
4. The increase of pBDNF at week 1 compared to baseline
5. The increase of sBDNF at week 1 compared to baseline

Key secondary outcome(s))

The correlation of predictors value change at week 1 or 2 and the change of MADRS score at the end of study.

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients suffering from Major depressive disorder (recurrent or single episode) diagnosed according to Diagnostic and Statistical Manual of the American Psychiatric Association-IV. revision (DSM-IV) criteria, confirmed using The Mini-International Neuropsychiatric Interview - M. I.N.I., Czech version 5.0.0.
2. Patients fulfilling at least Stage I (≥1 previous, unsuccessful, adequate, antidepressant treatment) criteria for resistant depression according to Thase and Rush.
3. The mental ability to understand and sign Informed Consent Form.
4. The score in the Montgomery and Åsberg Rating Scale (MADRS) ≥25 and the score in Clinical Global Impression (CGI)≥4.
5. Inpatients.
6. Age between 18 and 65 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Contraindications of treatment with selective serotonin reuptake inhibitors (SSRIs) (citalopram, escitalopram, fluoxetine, fluvoxamine, sertraline, paroxetine) according to Summary of Product (SPC)
2. Psychiatric comorbidity on axis I and II according to DSM IV in the 6 months before enrollment to the study
3. Patients with severe somatic disorders (cardiovascular disease, neoplasms, endocrinology disorders etc.) that could be associated with depression due to somatic disease.
4. Patients treated with electroconvulsive therapy less than 3 month before enrollment or suffering from neurologic disorder (e.g., epilepsy, head trauma with loss of consciousness) and patients using any treatment which can strongly affect EEG.
5. Patients who were treated unsuccessfully with more than one SSRIs during index episode.

Date of first enrolment
01/05/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
Prague Psychiatric Center
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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
Internal Grant Agency of Ministry of Health of Czech Republic grant ref: IGA MZ CR NT 14287

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	01/08/2017	22/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes