Influence of stress vulnerability on type and course of bipolar disorder

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1. Define risk profiles based on retrospective data in a cohort of bipolar patients. These profiles will be based on the effects of various combinations of MR and GR genotypes involved in stress regulation on symptoms, course of the illness and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON31247

Source
ToetsingOnline

Brief title
BIpolarity and Stress Study, BISStudy

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder, manic depressive illness

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bipolar disorder, neurocognitive deficits, polymorphisms, stress

Outcome measures

Primary outcome

In the cross sectional approach outcome measures will be neurocognitive

functioning, defined by the neurocognitive tests, genotype and diagnosis,

defined by the MINI.

The Life Chart Method is the main outcome measure (of functioning and symptoms)

for the prospective approach.

Secondary outcome

The SSL and SLE are mediators of outcome

Study description

Background summary

Stress causes a spectrum of autonomic, endocrine and behavioural responses. There is ample evidence that bipolar disorder is associated with a chronic dysregulation of the Hypothalamic- Pituitary- Adrenal axis. Cortisol is the central hormone in the stress-response and has its effect through the Mineralocorticoid Receptor (MR) and the Glucocorticoid Receptor (GR). Recently, several polymorphisms of both the MR and GR have been found to be associated with dysregulation of the HPA-axis and with mood disorders. Results of an earlier study performed by us confirmed the impact of the ER22/23EK polymorphism and the 9beta polymorphism on course and symptoms(Spijker et al 2007)

Study objective

1. Define risk profiles based on retrospective data in a cohort of bipolar patients. These profiles will be based on the effects of various combinations of MR and GR genotypes involved in stress regulation on symptoms, course of the illness and neurocognitive functioning.

2. A prospective study involving the above mentioned cohort and a cohort of recently diagnosed patients. We will investigate whether the GR and MR polymorphisms are able to predict the course of the disease in this cohort and in a second cohort of newly diagnosed patients prospectively. The influence of life events and social support in relation to genotype and symptoms and course of the disorder will be measured.

The influence of GR and MR on neurocognitive functioning will be tested also. This part of the study will be described in a future addendum.

The results of this research will be highly relevant in understanding the relation between stress and psychopathology, and give impetus to new forms of therapy. It will enable clinicians to early identify patients with a high risk on a bad prognosis of the illness and thereby possibilities for early prevention.

Study design

This study consists of both a cross-sectional and prospective approach including 400 patients with bipolar disorder. In the cross-sectional approach, all patients will be interviewed and neurocognitively tested to define phenotype and endophenotype; a blood sample will be taken to analyse genotypes of cortisol receptors.
In the prospective approach two cohorts of patients will be followed for three years to monitor course of the illness through the Life Chart Method, the Social Support List and Serious Life Event Scale. Cohort A exists of all patients included in the cross-sectional part of the study, we expect to include around 200 for the prospective part of the study. Cohort B exists of patients with recently diagnosed bipolar disorder, we expect to include around 200 patients for the prospective part of the study.
Neurocognitive testing of all patients will be described in a future addendum. From a subgroup of patients, first degree family members will be asked to participate in the study. This part of the study will also be described in detail in a future addendum

Study burden and risks

Of all patients one blood sample is needed. This is in the patients group almost completed, as we studied the relation between genotypes and phenotype of bipolar disorder last year . In the cross-sectional approach (phase 1) all patients need to come for an interview for about an hour to complete questionnaires and a short neurocognitive attention test. In the subgroup of patients and their first degree relatives phenotype will be defined by the Symptom Checklist and the MINI. Genotyping of GR and MR will be performed in patients and their first degree relatives.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

bipolar disorder

Exclusion criteria

younger than 18 years old, schizoaffective disorder

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	400
Type:	Actual

Medical products/devices used

Generic name:	Life Chart Method
Registration:	No

Ethics review

Approved WMO

Date:	12-12-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18286.097.07