Influence of stress vulnerability on type and course of bipolar disorder.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23244

Source
NTR

Brief title
BIpolarity and Stress Study, BISStudy

Health condition

Bipolar Disorder

Sponsors and support

Primary sponsor: Parnassia Bavo Groep/ PsyQ The Hague
Erasmus MC Rotterdam
LUMC
Source(s) of monetary or material Support: Nuts Ohra
PsyQ The Hague

Intervention

Outcome measures

Primary outcome

Number of episodes.

Secondary outcome

1. Cognitive performance;

2. Physical health (parameters of metabolic syndrome).

Study description

Background summary

Background of the study:

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.

Objective of the study:

Its aim is to evaluate the effect of genotypes on symptoms, neurocognitive functioning and course of the illness. A smaller subgroup of the cross-sectionally assessed patients and their siblings will be evaluated for relations between deficits in attention and memory, HPA-axis functioning and polymorphisms. 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.

Study design:

This study consists of both a cross-sectional and prospective approach including 300 patients with bipolar disorder. In the cross-sectional approach, all patients and healthy volunteers will be interviewed and neurocognitively tested to define phenotype and endophenotype; a blood sample will be taken to analyse genotypes of cortisol receptors. A subgroup patients with the ER22/23EK polymorphism and the 9beta polymorphism of the Glucocorticoid Receptor and their first degree relatives will be extensively studied for neurocognitive functioning by the Testbatterie fur Aufmerksamkeitsprufung (TAP), cortisol levels through a Dexamethason Suppression Test, and clinical symptoms through the Mini International Neuropsychiatric Interview (MINI) and the Symptom Checklist.

In the prospective approach all 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.

Study population:

Study population: The study population consists of 300 patients with bipolar disorder. Patients with a schizo-affective disorder are excluded. All patients are older than 18. A group of 300 healthy volunteers will be used as control group.

Primary study parameters/outcome of the study:

Life Chart Method is the main outcome measure for the prospective approach, the SSL and SLE Scale are secondary outcome measures. In the cross sectional approach outcome measures will be neurocognitive functioning, defined by the Divided Attention Test, genotype and diagnosis, defined by the MINI. In the subgroup of patients and their first degree relatives primary outcome measures are the MINI and SCL, the TAP, cortisol levels and the genotypes.

Secundary study parameters/outcome of the study:

DST, Neurocognitive functioning.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Of all patients and healthy volunteers one blood sample is needed. This is in the patients group almost completed, as we studied the relation between genotypes and fenotype of bipolar disorder last year (number...). In the cross-sectional approach 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 fenotype will be defined by the Symptom Checklist and the MINI, endophenotype will be studied by.

In the prospective study all patients will have to come every three months for an interview of about 15 minutes, as much as possible combines with their regular appointments with their clinician. They have to fill in 2 questionnaires and the life chart, together with a research nurse. After that the life chart will be also therapeutically used during the appointment with the clinician .

Study objective

Stress vulnerability as reflected by cortisolreceptor gene polymorphisms, influences course of bipolar disorder defined by number of episodes, physical health and cognitive functioning.

Study design

Every 3 months during 2 years.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Bipolar Disorder;

2. Older than 18 years.

Exclusion criteria

Schizoaffective disorder.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	26-07-2010
Application type:	First submission

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
NTR-new	NL2323
NTR-old	NTR2429
Other	ABR / CCMO : 18286 / NL18286.097.07 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Functional polymorphism of the
glucocorticoid receptor gene associates with
mania and hypomania in bipolar disorder; Bipolar Disorders 2009: 11: 95–101