Extent and kind of cognitieve dysfunctions in patients suffering from bipolar disorder: their determinants and impact on clinical and functional outcome

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Ethical review	-
Status	Pending
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON47826

Source
ToetsingOnline

Brief title
Cognition in bipolar disorder

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
manic depressive disorder; bipolar disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,Astra Zeneca,Young investigators grant van Astra Zeneca

Intervention

Keyword: bipolar disorder, cognition, functional outcome, HPA axis

Outcome measures

Primary outcome

The main study endpoint is cognitive dysfunction, defined as a score of 2 standard deviations (SD) below the average of the healthy control group in one of the cognitive tasks.

Secondary outcome

- Clinical factors: Illness characteristics (medical history (for example number of episodes), medication
- Biological factor: HPA axis functioning, neuroinflammation markers and markers of intestinal permeability in blood
- Outcome factors: psychosocial outcome (WHO-DAS II, ZW, RAND, WHO-Qol-Bref, GAF), illness outcome (course of illness (number of episodes), insight (Mood Disorders Insight Scale), traumatic life-events

Study description

Background summary

Cognitive dysfunctions have increasingly become a focus of research in bipolar disorders. It is estimated that one-third of patients with bipolar disorder suffer from cognitive dysfunctions, even in a clinically asymptomatic phase. However, due to relatively few studies and many methodological pitfalls, the exact extent and kind of cognitive dysfunctions in bipolar disorders, as well as information about the suspected clinical and biological determinants remains unclear. Also, the relationship between cognitive dysfunctions and clinical and

functional outcome parameters are understudied. More knowledge could lead to an addendum of the standard assessment in patients with bipolar disorder (like schizophrenic patients), and may possible result in new therapeutic approaches to improve quality of care, better treatment adherence and ultimately better functional outcome.

Study objective

The primary objective is the extent and kind of cognitive deficits in patients suffering from bipolar disorders compared to healthy controls and patients with a lifetime diagnosis of unipolar depressive disorder. Secondary objectives specify the clinical possible determinants of cognitive dysfunctions (for example illness and patient characteristics and HPA axis functioning) and the (possible) consequences of cognitive dysfunctions (psychosocial functioning and illness outcome).

Study design

Cross sectional design

Study burden and risks

This study is an enlargment of a previous approved study (METC 2005/236). This project only requires one extra visit to the UMC Groningen. The total study will be performed by patients in around 5 hours and by healthy controls in 3 hours, including the cognitive tests, evaluation of patient- and illness characteristics and outcome measurements (partly by interview, partly by questionnaires), venapuncture and saliva samples performance to perform cortisol measurements. The participation in venapuncture of 1 tube of 10 cc. to collect a reserve sample has minimum risks. Saliva sampling itself takes place at home and only requires a minimum of time (maximum of 20 minutes) in 2 consecutive days. During saliva sampling patients are asked to ingest 0.5 mg dexamethason, which is not a harmful drug that inhibits the release of cortisol for a maximum of 24 hours and rarely causes the next morning a higher level of alertness, comparable with the intake of one cup of coffee.

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

- MINI-plus confirmed diagnosis of bipolar disorder
- minimum age 18 years; maximum age 65 years
- IDS-SR <34 (i.e. not severly depressed) + YMRS <8 (not (hypo)manic)

Exclusion criteria

-mental retardation
- a known systemic or neurological illness, known to affect cognitive functioning

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL18530.042.07