Diagnostic Imaging of Affective Disorders using Emotion-processing in non-depressed patients (DIADE-II). A neuroimaging study to determine biomarkers to discriminate unipolar and bipolar depression

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Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON36176

Source
ToetsingOnline

Brief title
DIADE-II

Condition

- Mood disorders and disturbances NEC

Synonym
bipolar disorder, depression, mood disorders

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: bipolar disorder, diagnosis, fMRI, major depressive disorder

Outcome measures

Primary outcome

We will compare performance on the exogenous curing task between MDD, BD and HC, measured by response time, number of omissions and number of errors. The same outcome will be examined for the neuroimaging tasks. We will compare brain responses of fMRI tasks relative to control conditions between MDD, BD and HC. We will compare responses in predefined ventral and dorsal brain regions (dorsolateral prefontal cortex (PFC) ventral PFC, orbitofrontal, limbic and subcortical regions).

Secondary outcome

not applicable

Study description

Background summary

The study concerns the diagnosis of major depressive disorder (MDD) and bipolar disorder (BD). Early differentation between both disorders is very important, since treatments differ, and providing the wrong therapy is associated with prolonged illness duration and recurrence. However the diagnosis is often unclear due to the fact that ; (1) clinical characteristics of a major depressive episode (MDE) in both diosorders is not clearly discriminate, (2)

retrospective assesments of a (hypo)manic episodeis usually equivocal and (3) (hypo)manic episodes may occur long after the first MDE. Current diagnostic tools (i.e. questionaires and interviews) are rather insensitive, rendering a diagnostic grey zone of false negative diagnosis for BD. Therefor additional diagnostic procedures are required. At best, this could be procedures to indentify disease specific brain-processes (biomarkers). Since findings from recent affective neuropychological and fMRI sutdies indicate differences in emotional processing between MDD and BD, these instruments are promising candidates for detecting such biomarkers. Until now, only two studies directly compared MDD and depressed BD with healthy controls (HC). Furthermore, in most studies, medication use was allowed, which may have been an important confounder. to investigate the value of neuropsychological testing and/or fMRI for diagnosis, new studies and replications of earlier research of these biomarkers are needed, preferably in direct comparisons of unmedicate MDD and BD patients versus HC.

Study objective

We aim to (1) improve differential diagnosis of recurrent MDD and BD by investigating biomarkers at a neuropsychological and neurobiological level ; (2) investigate whether affective neuropsychological testing can be used as a diagnosios tool for MDD and BD; and (3) investigate whether fMRI can be used for this purpose.

Study design

The study is a cross sectional study with prospective follow up for a period of 2.5 years in an outpatient

Study burden and risks

There is no immediatly advantage for the participants. All depressed patients will be offered treatment according to treatment guidelines. On the other hand, the study is neither very burdensome, nor does it carry major health risk.

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

All MDD and BD I and BD II patients of both sexes: age 18-60 years; at least 2 MDEs, with remission between episodes; age of first episode * 40 years; illness duration of * 5 years since the first episode.
Non-depressed MDD and BD patients: no diagnosis of major depressieve episode (MDE) at time of baseline (according to SCID)
In addition, for BD: at least one manic episode (assessed by SCID) not solely during the use of antidepressants.
Healthy controls: age 18-60 years; euthymia at time of baseline (According to SCID; Inventory for Depressive Symptoms (IDS) *14)

Exclusion criteria

MDD and BD I / II patients: electroconvulsive therapy within 2 months before scanning; current (hypo)mania (Young Mania Rating Scale (YMRS) > 8; at study entry or within the previous month before baseline); a current depressive episode according to the SCID or a HDRS>16; atypical depressive symptomatology; concurrent co-morbid Axis I diagnosis; a clear clinical diagnosis of cluster B personality disorder (assessed by previous documentation and/or a history of recurrent suicidal and parasuicidal acts); currently using psychopharmacological medication (antidepressants, anticonvulsants or mood-stabilizers stopped *1 month before scanning). Incidental benzodiazepine use will be allowed, but must be stopped before scanning.

In addition, for MDD: a history of (hypo)manic derailment after antidepressant use; a family history of bipolar disorder.
HC: a lifetime psychiatric diagnosis (axis I, assessed by SCID); a current diagnosis of alcohol or drug dependence; first-degree relatives with a history of a psychiatric diagnosis; use of any psychopharmacological agent.
All subjects: a history of head trauma or neurological disease; severe general physical illness; claustrophobia or implanted metal objects.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-03-2011
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL36226.018.11