Improvement of diagnosis of major depressive and bipolar disorder: an fMRI-study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21341

Source
NTR

Brief title
DIADE

Health condition

major depressive disorder
bipolar disorder
diagnosis
fMRI

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

We will compare performance on the neuropsychological task between MDD, BD I and HC, measured by reponse time, number of omissions and number of errors. The same outcomes will be examined fot 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 prefrontal cortex (PFC), ventral PFC, orbitofrontal, limbic and subcortical regions).

Secondary outcome

N/A

Study description

Background summary

BACKGROUND:
The study concerns the diagnosis of major depressive disorder (MDD) and bipolar disorder (BD). Early differentiation between both disorders is very important, since treatments differ, and providing the wrong therapy is associated with prolonged illness duration and recurrence. However, when a patient presents with a major depressive episode (MDE), diagnosis is often unclear due to the fact that:

1. Clinical characteristics of MDE in both disorders do not clearly discriminate;

2. Retrospective assessment of a (hypo)manic episode is usually equivocal, and;

3. (Hypo)manic episodes may occur long after the first MDE.
Current diagnostivc tools (i.e., questionnaires and interviews) are rather insensitive, rendering a diagnostic grey zone of false negative diagnosis for BD. Therefore additional diagnostic procedures are required. At best, this could be procedures to identify disease specfic brain processes (biomarkers). Since findings from recent affective neuropsychological and fMRI studies 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 iimportant 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 unmedicated MDD and BD patients versus HC.
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 diagnostic tool for MDD and BD;

3. Investigate wether fMRI can be used for this purpose.
DESIGN:
The study is a cross sectional study with proscpective follow up for a period of 2.5 years in an outpatient population.
STUDY POPULATION:
We will investigate three subject groups: 20 MDD, 20 BD I, and 40 HC. Patients will be medication free, aged 20-60 years, currently moderately to severly depressed, with a history of at least 2 MDEs. HC will be matched on sex, age, handedness and years of education.
PRIMARY OUTCOME:
We will compare performance on the neuropsychological task between MDD, BD I and HC, measured by reponse time, number of omissions and number of errors. The same outcomes 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 prefrontal cortex (PFC), ventral PFC, orbitofrontal, limbic and subcortical regions).
RISKS AND BENEFITS:
There is no immediate advantage for the participants. All depresed patients will be offered treatment according to treatment guidelines. On the other hand, the study is neither very burdensome, nor does it carry a major health risk.

Study objective

By detection of disease specific deviations in emotion processing in unipolar vs bipolar patients, affective neuropsychological tests and fMRI could be used to discriminate between both affective disorders.

Study design

1. Intake and scan session (within 1 week);

2. Follow up for 30 months: telephone contact every 6 months.

Intervention

1. Questionnaire;

2. Psychiatric interview;

3. Affective neuropsychological testing;

4. fMRI;

5. Venapunction.

Contacts

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Eligibility criteria

Inclusion criteria

1. Major depressive disorder (MDD) and Bipolar I and Bipolar II (BD I and BD II) patiens of both sexes;

2. Age 18-60 years;

3. Various levels of depressive symptomatology, ranging from moderate to severe (HDRS score at least 16);

4. At least 2 major depressive episodes, with remission between episodes;

5. Age of first episode younger than 40 years;

6. Illness duration of at least 5 years since first episode.

In addition, for BD I and BD II:

7. At least one (hypo)manic episode (assessed by SCID) not solely during the use of antidepressants;

Healthy controls (HC):

1. Age 20-60 years;

2. Euthymia at time of baseline (IDS less than 14).

Exclusion criteria

MDD and BD I and BD II patients:

1. Electroconvulsive therapy within two months before scanning;

2. Current (hypo)mania (YMRS above 8; at study entry or within the previous month before baseline);

3. Atypical depressive symptomatology;

4. Concurrent comorbid axis I diagnosis;

5. A clear clinical diagnosis of cluster B personality disorder;

6. Currently using psychopharmacological medication (antidepressants, anticonvulsants or mood stabilizers stopped less than 2 months before scanning).

Incidental benzodiazepine use will be allowed, but must be stopped before scanning.

In addition, for MDD:

1. A history of (hypo)manic derailment after antidepressant use;

2. A family history of bipolar disorder.

Healty Controls:

1. A lifetime psychiatric diagnosis (axis I, assessed by SCID);

2. A current diagnosis of alcohol or drug dependence;

3. First degree relatives with a history of psychiatric diagnosis;

4. Use of any psychopharmacological agent.

All subjects:

1. A history of head trauma or neurological disease;

2. Severe general physical illness;

3. Claustrophobia or implanted metal. objects.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-04-2009
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	NL1663
NTR-old	NTR1763
Other	ABR nr / CCMO / ZonMw : 24252 / versie 2 / 100-002-034
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A