Structural brain changes in bipolar disorder

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

Summary

ID

NL-OMON38291

Source
ToetsingOnline

Brief title
Structural brain changes in bipolar disorder

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder, manic depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Dit onderzoek wordt gesubsidieerd door de National Institute of Mental Health.

Intervention

Keyword: bipolar disorder, imaging genetics, structural MRI

Outcome measures

Primary outcome

The main studyparameter is structural abnormalities in the brain of bipolar patients, compared to unrelated healthy controls.

These structural differences will be measured by;

- Brain volume (sMRI) and density (voxelbased morphometry)

- Fractional anisotropy and magnetisation transfer ratio

Secondary outcome

The secondary parameter is data that associates the structural data with genetic data.

Furthermore, we will also study baseline values or parameters which might intervene with the main study parameter, like age, gender, years of education, symptoms, level of functioning, medication intake and life events. We are mainly interested in the effect op medication on the bipolar brain.

Study description

Background summary

Bipolar disorder is a complex psychiatric trait with unknown etiology. In addition to genome wide association studies, it is important to investigate other possible phenotypes of bipolar disorder. Endophenotypes are measurable intermediate phenotypes that are generally closer to the action of the gene and therefore easier to notice. Structural brain abnormalities are associated with bipolar disorder and can provide such an intermediate phenotype of bipolar disorder.

Study objective

The main goal of this study is to recruit and obtain magnetic resonance images in a large sample of bipolar patients and controls from the Netherlands, in order to find brain abnormalities specific for bipolar disorder. We will also perform genetic imaging to identify the genes that regulate brain architecture and investigate how brain abnormalities are associated with the genetic susceptibility to bipolar disorder. Furthermore we would also like to investigate the effects of medication on the brains of patients. This might shed a light on the effects of lithium and other drugs on the bipolar brain.

Study design

In this case control study we compare measures of brain structure obtained with Magnetic Resonance Imaging in 300 bipolar patients with 300 healthy controls and investigate association to genome wide genotype information obtained in a large genome wide association study.
Four years are needed to complete recruitment, scanning and sample collection of all the subjects. Statistical analyses are initiated in the fourth year and continue in year five.

Study burden and risks

The risks associated with participation and the benefits to the individual are felt to be minimal. MRI is a non-invasive technique, with no known risks for the participants. Participation will take 1.5 hours. Besides financial remuneration, no immediate benefits are to be expected from participation in this study for the subjects themselves. However, for society, increased understanding of the underlying causes of BD and the genetics and brain processes involved in BD may contribute to diagnosis, early detection and/or prediction of treatment outcome.
As the project involves minimal risk to participants, and as the potential benefits in terms of knowledge gained are quite large, the benefits clearly outweigh the risks.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with bipolar disorder
- A diagnosis of BD-I according to the DSM IV, with at least one clinical intervention for mania (DSM-IV criteria)
- No history of Cognitive Disorder (DSM-IV criteria)
- Age >= 18 years
- Dutch ancestry (at least three of the four grandparents from the Netherlands);Healthy controls
- Age >= 18 years
- Dutch ancestry (at least three of the four grandparents from the Netherlands)
- No history of bipolar disorder, schizophrenia or other psychotic disorder (DSM-IV criteria)
- No first degree relative with a history of bipolar disorder, schizophrenia or other psychotic disorders (DSM-IV criteria), on the basis of a FIGS interview

Exclusion criteria

- Premorbid IQ < 80
- Did not give written informed consent
- Ferrous objects in or around the body
- Drug or alcohol abuse over a period of six months prior to the experiment (DSM-IV criteria)
- History of closed-head injury
- History of neurological illness or endocrinological dysfunction

- Claustrophobia
- Severe medical illness
- Current treatment or detention under the Dutch governmental mental health act.
- Participants that cannot read, speak or understand Dutch.

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:	Recruitment stopped
Start date (anticipated):	16-06-2011
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2011
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-10-2012
Application type:	Amendment
Review commission:	METC NedMec

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	NL34555.041.10