Biomarkers and Mood course in Bipolar disorder in the Netherlands - a Longitudinal Cohort study (BINCO)

Published: 07-01-2016
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Primary Objective: To identify immuno-endocrine and neuro-imaging parameters differentiating between different mood states (manic, depressive, and euthymic). Secondary Objectives: 1. To identify the influence of these parameters on the onset and...

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

Summary

ID

NL-OMON50605

Source
ToetsingOnline

Brief title
BINCO

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder; manic depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: psychiatrie
Source(s) of monetary or material Support: Danone Vitapole,LUMC;FSW Leiden;PsyQ;andere subsidies worden aangevraagd

Intervention

Keyword: biomarkers, bipolar disorder, longitudinal, mood episodes

Outcome measures

Primary outcome

Primary study parameters of the current study include therapeutic outcome variables, i.e. severity of depressive (measured by the QIDS) and manic (YMRS) symptoms.

Secondary outcome

Secondary study parameters include psychological variables such as irritability (IS-SR), personality factors, stressors (PSS), attachment (ECR), cognitive functioning (WAIS-R), early life trauma (CTQ), symptoms of PTSD (ZIL) and daily functioning (OQ).

Additionally several neurobiological variables will be assessed through blood sampling, including immuno-endocrine markers, gonadal hormones and markers of metabolic syndrome.

Further, through the use of hair sampling, longitudinal assessments of cortisol levels will be conducted.

Lastly, participants will also be invited to participate in an MRI substudy.
The imaging brain results will be related to the longitudinal mood course and treatment response.

Study description

Background summary

Bipolar disorder is a chronic disabling disease with an intermittent course and constitutes a serious burden on patients, family and society. One of the main problems in the treatment of patients with a bipolar disorder is how little is known about the underlying (biological) mechanisms that contribute to the complex interplay between the environment (e.g. stressful events, trauma) and severity and recurrence of mood episodes. Knowledge about the neurobiology underlying mood episodes in bipolar disorder is highly needed in order to improve the quality of care for these patients.

Study objective

Primary Objective:
To identify immuno-endocrine and neuro-imaging parameters differentiating between different mood states (manic, depressive, and euthymic).

Secondary Objectives:
1. To identify the influence of these parameters on the onset and course of new mood episodes.
2. To identify biological parameters differentiating in risk of relapse in the course of bipolar disorder.
3. To identify neuroendocrine, immunological an neuro-imaging mechanisms involved in the onset and course of mood episodes compared to stable periods.
4. To identify the influence of life style factors such as dietary intake components, and gut microbiota on mood state.
5. To identify the influence of sex hormones on mood episodes
6. To identify the relation of cognitive functioning on relapse risk

Study design

This study is a longitudinal naturalistic study, with a prospective cohort study design. Patients with bipolar disorder will be followed during 1 year, which will be extended coming years.

Study burden and risks

The main study parameters are assessed using standardized self-rating questionnaires as well as periodical blood and hair sampling. As such, the overall risks associated with participation are minimal for the individual. There is no benefit for the individual patients, but the potential benefit to society and wellbeing for patients with a bipolar disorder can be considerable.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients
- Diagnosed with bipolar disorder type I and II according the SCID-I (diagnosis < 1 year)
- Aged above 18 , One of out of 2 criteria below:
- Start of specialized outpatient treatment
- Admission due to depression or mania, Healthy controls:
-matched on age and gender with patient population

Exclusion criteria

Patients

- Current treatment or detention under the Dutch governmental mental health act.
- Participants that cannot read, speak or understand Dutch.
- Aged below 18
- Diagnosed with bipolar disorder NOS or cyclothymic disorder., For MRI scanning:
- Ferrous objects in or around the body (e.g. braces, glasses, pacemaker, metal fragments)
- History of closed- or open-head injury
- History of neurological illness or endocrinological dysfunction with CNS sequelae
- Claustrophobia
- History of epilepsy
- Drug or alcohol abuse over a period of six months prior to the experiment , Healthy controls:
- no current psychiatric disorders accorrding to the DSM IV

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2016
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	11-09-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	24-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	01-02-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	16-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	02-04-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51776.058.14