MOODINFLAME - Early diagnosis, treatment and prevention of mood disorders targeting the activated inflammatory response system - Bipolar patients cohort

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To evaluate two biomarker tests (characterized by an activated inflammatory response system (IRS) as reflected by an aberrant monocyte gene expression signature and/or a disturbed metabolism of tryptophan) by comparing patients with BD with healthy...

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON33414

Source
ToetsingOnline

Brief title
MOODINFLAME - Bipolar patients

Condition

- Autoimmune disorders
- Ancillary infectious topics
- Manic and bipolar mood disorders and disturbances

Synonym
Bipolar disorder; manic-depressive illness

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Bipolar disorders, Immunology, Inflammation, Mood disorders

Outcome measures

Primary outcome

Percentages of patients and controls with positively expressed genes in the

monocytes and aberrant tryptophan parameters (positive/aberrant being defined

as over one standard deviation of the level found in healthy controls).

Secondary outcome

Gene polymorphism determination and the various cytokine and S100 and BDNF

determinations on the collected blood cells and HPA axis activity.

Determine microglia activation in brain using PET.

Study description

Background summary

Bipolar disorder (BD) with a lifetime prevalence of 2% is characterized by episodic pathologic disturbances in mood ranging from extreme elation (mania) to severe depression. There is no (biological) diagnostic marker for BD. Nevertheless, several findings have been found to be associated with BD: hypothalamic-pituitary-adrenal (HPA) axis disturbances; a higher frequency of autoimmune diseases; an increase of pro-inflammatory monocyte/macrophage cytokines; a pro-inflammatory gene signature in the circulating monocytes (and a PDE4B associated pro-inflammatory signature); an activated inflammatory response system (IRS) and glucocorticoid insensitivity with a linkage between an activated IRS, disturbances in the tryptophan metabolism, and immune activation of microglia cells in brain.

Study objective

To evaluate two biomarker tests (characterized by an activated inflammatory response system (IRS) as reflected by an aberrant monocyte gene expression signature and/or a disturbed metabolism of tryptophan) by comparing patients with BD with healthy controls (as well as other cohorts of MOODINFLAME, i.e. patients with major depressive disorder and with post-partum mood disorders and with individuals at risk for the development of BD, i.e. children of a parent with BD and unaffected (discordant) co-twins from a twin with BD).

Study design

Een crosssectionele casus-controle studie.

Study burden and risks

Participants will undergo an extensive psychiatric interview, will be asked to complete various questionnaires, will be asked to consent with reviewing existing medical records, will deliver 50 ml of blood, and will undergo a dexamethason suppression test (DST). The study provides no benefits for the participants with exception of the discovery of possible unexpected findings during the interview and or via the blood test. If such finding is relevant for the participant, in mutual arrangement his/her treating physician will be informed about this finding.
The study has no risks, with the exception of a minimal risk associated with the taking of a single blood sample.
The small number of patients/volunteers that give additional approval to receive a PET scan, will be exposed to a small to intermediate radiation risk and small risk by arterial cannulation of the radial artery. From this cannula 160ml blood will be withdrawn in the course of 1 hour with no detrimental effects to be expected.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713 GZ Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1

9713 GZ Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
18-65 years
Both male and female
Bipolar I disorder or Bipolar II disorder
Preferentially euthymic (IDS-C <22 and YMRS <12)
No other primary major psychiatric diagnosis (e.g. primary psychotic disorder, schizo-affective disorder, primary anxiety disorder)
No current severe alcohol or other substance use disorder, needing treatment in a specialized setting
No alcohol or other substance dependence in the last year
No current or recent (last 4 weeks) severe infectious or inflammatory disease
No known current uncontrolled systemic disease (e.g. LE, RA)
No known major uncontrolled metabolic disorder (e.g. diabetes, hyper- or hypothyroidism, Cushing disease of Addison disease)
No known other significant uncontrolled somatic/organic/neurological disorder which may cause/affect mood
No current or recent (last month) use of somatic medication which may affect mood or the immune system (e.g. corticoids, anti-inflammatory drugs, immune suppressive drugs)
Women: Not pregnant or recent (<6 months) delivery
Informed consent

Healthy controls:
To be collected at same site
Age matched (within 5 years)
Gender matched

Sampling time matched (within 6 months)
18-65 years
Both male and female
No relevant present psychopathology
No major axis I disorder, e.g. MDD, bipolar disorder, psychotic disorder, schizo-affective disorder, anxiety disorder, alcohol or other substance dependence (lifetime)
For women: No prior PP depression/psychosis
No current alcohol or other substance use disorder
No current or recent (last 4 weeks) severe infectious or inflammatory disease
No known current uncontrolled systemic diseases (e.g. LE, RA)
No known major uncontrolled metabolic disorder (e.g. uncontrolled diabetes, hyper- or hypothyroidism, Cushing disease of Addison disease)
No known other significant somatic/organic/neurological disorder which may cause/affect mood
No current or previous psychiatric treatment/medication
No current or recent (last month) use of somatic medication which may affect mood or the immune system (e.g. corticoids, anti-inflammatory drugs, immune suppressive drugs)
Not pregnant or recent (<6 months) delivery
Informed consent
For PET imaging with MRI: No magnetizable metal in body, no pregnancy, adequate birth contol, no current use of benzodiazepines, no use of anticoagulants, and additional informed consent

Exclusion criteria

See inclusion criteria

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-03-2009
Enrollment:	240
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
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	NL26374.042.09