MOODSTRATIFICATION
Immune Signatures for Therapy Stratification in Major Mood Disorders

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON48608

Source
ToetsingOnline

Brief title
MOODSTRATIFICATION

Condition

- Autoimmune disorders
- Ancillary infectious topics
- Mood disorders and disturbances NEC

Synonym
auto - immune diseases, mood disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Europese Unie [horizon2020]

Intervention

Keyword: Bipolar disorders, depression, Immunology, Inflammation, Mood disorders

Outcome measures

Primary outcome

The primary outcome is treatment response to 8 weeks of care as usual. We define treatment response based on the improvement in the HDRS17 across this period with a * 50% decrease in HDRS17 total score indicating full response and a 25-49% decrease in the HDRS17 total score indicating partial response.

Secondary outcome

Secondary study endpoints are:

- changes in IDS-SR total sum score after 8 weeks.

- changes in BSS total sum score after 8 weeks.

- changes in BAI total sum score after 8 weeks.

Study description

Background summary

Psychiatric disorders are the largest cause of disability in working age individuals in Europe, defining a major public health and economic need in our age. Major Depressive Disorder is projected to be the second most disabling medical condition worldwide by year 2020, and Bipolar disorder is not far behind. Although effective therapies are available to many patients with mood disorders in EU countries, their overall prognosis is far from optimal. One of the major challenges is the heterogeneity in current classifications of mental disorders in terms of both clinical aspects and underlying pathophysiological mechanisms such as dysregulations in the immune system. Complex interactions of socio-demographic characteristics, clinical psychiatric and somatic features and immune system markers all influence the prognosis of depression but these are not all systematically assessed in research and clinical practice to help

obtain more effective, personalized treatments. Especially immune system markers seem promising as putative predictors of treatment outcome. A substantial portion of patients with mood disorders show distortions in their immune system, which is associated with a poor outcome of regular antidepressant treatment and emphasizes the need for further research on the relationship between the immune system, mood disorders and treatment.

Study objective

MOODSTRATIFICATION is a large, multi-center international study supported by the EU. Workpackage 3 aims to establish a proof-of-concept for a succesful therapy-stratification model for use in patients with a moderate to severe depressive episode. The primary aim of the first phase of this study is to systematically evaluated outcome of regular antidepressant treatment in patients with a depressive episode and gaining more insight in the functioning of the immune system of these patients in order to obtain more insight into the potential benefits of stratification model. In the last 2 years of the study, clinics will use a blood test guided approach for add-on therapy in patients with an active depressive episode using their immune signatures. In this protocol, we will only describe the details of the objectives and design of the study concerning the first two years of MOODSTRATIFICATION, which will be overseen by the university center of psychiatry in the UMCG.

Study design

A naturalistic follow-up study with a baseline assessment and follow-up assessments at week 0, 8
and 24.

Study burden and risks

Participants will undergo a psychiatric interview and will be asked to complete various questionnaires. At different time points during the study these activities may be experienced as boring and/or annoying, but this constitutes a negligible to mild burden. Patient will also deliver 50ml of blood . Taking a single blood sample is associated with a minimal risk. The study provides no benefits for the participants with exception of the discovery of possible unexpected findings during the interview and or the blood test. If such a finding is relevant for the participant, in mutual arrangement, their physician will be informed about this finding.

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

- Meets DSM-V criteria for MDD or BD established by MINI Plus
- Depression severity > 13 on the HDRS-17
- Age within the range of 18-65 years
- Already using an antidepressant and/or mood stabilizer without sufficient clinical response

Exclusion criteria

- Unable to provide informed consent
- Receiving care in the context of involuntary treatment and hospitalization.
- Existing or planned pregnancy or lactation
- Already participating in a other interventional study
- If at inclusion the planned next step of treatment will be ECT.
- Cancer or history of cancer in the last 5 years (except skin epidermoid cancer or in-situ cervix cancer).
- Current manic or mixed episode of bipolar disorders

- Current severe alcohol or other substance use disorder, needing treatment in a specialized setting
- Alcohol or other substance dependence in the last year which a patient needed treatment in a specialized setting.
- Current or recent (last 4 weeks) severe infectious or inflammatory disease
- Known current uncontrolled systemic disease (e.g. LE, RA)
- Known major uncontrolled metabolic disorder (e.g. diabetes, hyper- or hypothyroidism, Cushing disease of Addison disease)
- Known other significant uncontrolled somatic/organic/neurological disorder, such as or diabetes or stroke which may affect mood
- Current or recent (last 4 weeks) use of somatic medication which may affect mood or the immune system (e.g. corticoids, anti-inflammatory drugs, immune suppressive drugs)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-02-2019
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	NL66772.042.18