DOBi biobank: Biobank for Dutch Older Bipolar patients

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Primary: To further characterize a cohort of older patients with bipolar disorder, including clinical features, cognition, social functioning, need of care, family history and inflammation markers.Secondary: To investigate the effects of aging on...

Ethical review   Approved WMO
Status   Will not start
Health condition type   Manic and bipolar mood disorders and disturbances
Study type   Observational invasive

Summary

ID

NL-OMON44565

Source
ToetsingOnline

Brief title
DOBi biobank

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder, manic-depressive

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bipolar disorder, blood, genetics, older patients

Outcome measures

Primary outcome

exploration of relation between pro-inflammatory cytokines (IL-6) and stage of

bipolar disorder

Secondary outcome

Study description

Background summary

Despite the decreasing prevalence of bipolar disorder with age, the absolute number of bipolar elderly will increase substantially in the coming years due to ageing of the total population. To date research on characteristics, course and need of care is largely lacking, so to tailor psychiatric treatment programs for older patients with bipolar disorder research is is warranted. In 2012 we investigated 101 bipolar elderly patients attending an out-patient clinic by clinical interviewing to establish their psychopathology, social and cognitive functioning, quality of living and unmet needs in care.
Following our older bipolar patients over time will provide data on the effects of aging on their cognitive functioning, physical health and the course of their psychiatric symptoms. Our dynamic cohort will increase our statistical power to study older bipolar patients on different aspects and provide unique longitudinal data on these patients.
Next to questionnaires for clinical phenotyping we want to set up a rich biobank.

Study objective

Primary: To further characterize a cohort of older patients with bipolar disorder, including clinical features, cognition, social functioning, need of care, family history and inflammation markers.
Secondary: To investigate the effects of aging on cognitive functioning, physical health and the course of psychiatric symptoms in older patients with

bipolar disorder in a naturalistic longitudinal cohort.

Study design

Patients participating in DOBi, a dynamic cohort of older patients with bipolar disorder using questionnaires for clinical phenothyping will be requested to particpate.

Study burden and risks

There will be a one time blood draw of 18 ml. There is no risk as this will be combined with blood draw for regular care in most cases.

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

Patients will be included in the study only if the diagnostic procedure (described next) ascertained a diagnosis of bipolar 1 disorder (DSM-IV-TR: 296.00- .06, 296.40-.46, 296.50-.56, 296.60-.66, 296.7), bipolar 2 disorder (DSM-IV-TR: 296.89), or bipolar disorder NOS (DSM-IV-TR: 296.80).

Exclusion criteria

Patients unable to provide written informed consent due to inability to communicate in Dutch or English, mental retardation (defined as IQ below 70), poor cognition (Mini Mental State Examination (MMSE) below 18) or clinical diagnosis of dementia, or a highly unstable psychiatric condition (e.g. current compulsory admission) were excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	23-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62873.029.17