MASHBANK

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Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON30403

Source
ToetsingOnline

Brief title
MASHBANK

Condition

- Mood disorders and disturbances NEC

Synonym
MAS-disorders: mood- anxiety and somatoform disorders

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Rivierduinen

Intervention

Keyword: genetics, hpa-axis, psychiatry

Outcome measures

Primary outcome

The primary study parameters have not yet been established.

Secondary outcome

Not applicable

Study description

Background summary

Mood- Anxiety and Somatoform (MAS) disorders are highly prevalent psychiatric disorders with significant morbidity. The treatment succes is limited and recurrence rates are high. Genetic vulnerability and environmental influences are important precipitating factors in these disorders. Hyperactivity of the Hypothalamic-Pituitary-Adrenal (HPA) axis is found in more than half of the patients. Genetic variance in glucocorticoid receptors have been associated with regulation of the HPA-axis, and with the occurrence of MAS-disorders.
In Rivierduinen, a mental health organization in the Netherlands, and in the Leiden University Medical Center, department of psychiatry, all patients with MAS-disorders are extensively phenotyped with psychometric scales. This phenotyping is performed periodically, with the objective of monitoring of the treatment.

Study objective

The aim of this study is to investigate the role of the HPA-axis in MAS-disorders. By measuring cortisol in saliva the HPA-axis functioning can be determined (endophenotype), and by collecting buccal cells from which DNA will be isolated, single nucleotide polymorphisms in genes related to the HPA-axis can be identified (genotype).

Study design

Observational study

Study burden and risks

The MASHBANK-project will take approximately 30 minutes per patient. The collection of buccal cells will take place during a routine visit to the

psychiatric nurse. The collection of buccal cells may cause slight discomfort, but is in general not painful and it doesnt cause any bleeding.
The coolection of saliva will take place when the patient is at home. The patient has to chew on a swab on seven different time points. The saliva collection is not painful. For a dexamethasone-suppression-test it is necessary that the patient takes one tablet of dexamethasone 0,5 mg on one occasion. Side effects of this dose of dexamethasone are extremely rare. The total estimated time of the investigation is about 30 minutes.

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

Patiënts with depressive disorders, anxiety disorders or somatoform disorders, referred to the outpatients department of Rivierduinen or the LUMC.

Patiënts are 18 years or older.
Patiënts have provided written informed consent

Exclusion criteria

Patiënts who are younger than 18 years of age.
Patiënts who are unable to provide written informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	5000
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL14872.058.06