Neuroimaging of vulnerability for recurrence in major depressive disorder. A prospective neuroimaging study investigating neurobiological and psychoneuro-endocrinological mechanisms underlying recurrent Major Depressive Disorder and predicting recurrence.

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With this research-protocol we aim to investigate six important issues regarding recurrences of MDD-episodes:1. The differences between healthy controls and patients with recurrent MDD-episodes with respect to structural (sMRI) and functional (fMRI...

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

Summary

ID

NL-OMON35896

Source
ToetsingOnline

Brief title
DELTA-neuroimaging

Condition

- Mood disorders and disturbances NEC

Synonym
Depression; Major Depressive Disorder, recurrent type; Unipolar Depression

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Hersenstichting Nederland

Intervention

Keyword: Major Depressive Disorder, Neuroimaging, Psychoendocrinology, Recurrence

Outcome measures

Primary outcome

Measurements:

Two phases (study entry and after recurrence of depressive symptoms) are studied. In Phase I, two blocks of psychological tests will be obtained, followed by structural and functional magnetic resonance imaging (MRI). During the scanning, a mood induction will be performed. In Phase II, when patients experience a recurrence during follow-up, we will invite them for a new psychological test and an MRI-scan. At approximately the same moment during follow-up we will invite a matched patient (matched by age ±10 years and sex) who has not experienced a recurrence by then, for repeated testing as well.

Neuropsychological tests obtained are the Exogenous cueing task, Face recognition task, Emotional categorization task, Emotional Memory (both Phases) and the Dutch Adult Reading Test and the Negative affective priming (Phase I only).

MRI scanning will consist of a structural scan, resting state scan, Reinforcement learning task, Magnetic resonance spectroscopy, Diffusion Tensor Imaging, Emotional faces and Internal Shift Task (both Phases); in Phase I an Emotion regulation task and a repeated resting-state scan after a sad mood induction will be made.

Neurobiological/Neuroendocrine tests consist of blood collection for polyunsaturated fatty acids and brain derived neurotrophic factor, analysis of genetic polymorphisms and salivary cortisol measurements

Secondary outcome

Not applicable

Study description

Background summary

Major depressive disorder (MDD) is a highly prevalent and disabling disease, especially because its symptoms tend to return. In general antidepressants reduce the risk of recurrence 2-fold, but after cessation this risk appears to increase again. For prediction of recurrence, the number of previous episodes is amongst the strongest predictors, together with residual symptoms, *daily hassles* and coping style. Recurrence of MDD has been considered from neuropsychological, brain network dysfunction, neurochemical and psychoneuroendocrine perspectives which have not yet been integrated. Therefore, despite these perspectives of neurobiological substrates for recurrent depression, the underlying mechanisms of recurrence remain poorly understood, which will be improved by a multimodal approach in which neuroimaging will be combined with neuropsychological and neurobiological/neuroendocrine measurements in patients with recurrent depression.

Study objective

With this research-protocol we aim to investigate six important issues

regarding recurrences of MDD-episodes:
1. The differences between healthy controls and patients with recurrent MDD-episodes with respect to structural (sMRI) and functional (fMRI)-scans
2. The differences in changes in resting state activations and HPA-axis activity after mood-induction between remitted MDD-patients and controls
3. The differences in the relations between HPA-axis functioning, fatty acid status and neuroimaging findings between remitted MDD-patients and controls
4. The predictive value of sMRI/fMRI, changes in resting state activations and HPA-axis activity after mood-induction, fatty acid status and their interactions for the occurrence of new relapse/recurrences
5. The association between sMRI/fMRI, changes in resting state activations and HPA-axis activity after mood-induction and fatty acid status with the number of previous episodes
6. What changes occur in brain functions, psychoneuroendocrinological measures and their interaction when patients have a recurrence of their depression

Study design

Prospective and retrospective cohort design, with a healthy control comparison group, and an age and sex matched controlled repeated measurements design in case of future (non-) recurrence in the next 2.5 years

Study burden and risks

Not applicable

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

Remitted MDD-patients:
- Age 35-65 yr
- both sexes
- *2 MDD episodes according to a structured interview for DSM-IV (SCID)
- in stable remission defined as a Hamilton depression rating scale (HDRS) *7 and Inventory for depressive symptomatology (IDS-SR) *14 for at least 10 weeks.;Healthy controls: Controls will be matched with patients on age (±3 years), sex and estimated intelligence with the Dutch adult reading test (DART).
- matched for age, sex and years of education
- IDS-SR *14

Exclusion criteria

Remitted MDD-patients:
- current diagnosis of alcohol or drug dependence, psychotic or bipolar disorder, predominant anxiety disorder
- standard fMRI exclusion criteria (claustrophobia, implanted metal objects in the bodies)
- electroconvulsive therapy within two months before scanning
- a history of head trauma or neurological disease, severe general physical illness ;Healthy controls:
- Personal (assessed by SCID) or 1st degree relative with psychiatric disorder
- current diagnosis of alcohol or drug dependence
- standard fMRI exclusion criteria (claustrophobia, implanted metal objects in the bodies)
- a history of head trauma or neurological disease, severe general physical illness

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

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	NL35858.018.11