Somatic Depression in the Picture; a fMRI study comparing depression in patients with chronic kidney disease and depression in a regular outpatient population

Published: 04-04-2012
Last updated: 26-04-2024

To compare cerebral activity patterns during emotional and cognitive processing among depressed patients with CKD and patients with regular depression.

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

Summary

ID

NL-OMON39023

Source
ToetsingOnline

Brief title
Somatic depression in the picture

Condition

- Mood disorders and disturbances NEC
- Renal disorders (excl nephropathies)

Synonym
depression, depression with CKD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chronic kidney disease, cognition, Depression, emotion

Outcome measures

Primary outcome

Main study parameters are structural differences on MRI scans and signal change

in fMRI BOLD response to reward, self-evaluation and emotion regulation

processes as well as behavioural differences between groups in terms of

percentages correct and reaction times regarding the experimental tasks.

Secondary outcome

n.a.

Study description

Background summary

Depression is a frequent phenomenon in patients with CKD, experienced by 20-30% patients. Depression in these patients associated with a 2-2.5 fold increased hospitalization and mortality risk and a low quality of life. In the literature there is a discussion regarding inflated depression scores on self-report questionnaires in patients with a major somatic illness due to overlapping symptoms from the somatic illness and depression, such as fatigue. Therefore, we hypothesize that depression in patients with a major somatic illness is different from regular depression, i.e. a major depressive disorder not accompanied by another major somatic illness. Considering the high prevalence of depression in patients with CKD, this is an appropriate sample to investigate *somatic* depression. In order to be able to discriminate between both forms of depression and to better understand depression in patients with CKD, it is essential to study to what extent depression in patients with CKD differs from regular depression. In the future this may offer specific targets for the treatment of depression that occurs in patients with a major somatic

illness.

Study objective

To compare cerebral activity patterns during emotional and cognitive processing among depressed patients with CKD and patients with regular depression.

Study design

We will use: 1) fMRI to compare differences in cerebral activity in reaction to several cognitive tasks; 2) MRI to detect structural differences which might confound results of (1); 3) Cognitive tasks to detect cognitive impairments which might confound results of (1); 4) Questionnaires to precisely define the study population: the severity of depression (BDI-II), depression characteristics (fatigue, alexithymia, low self-esteem), psychiatric and cardiovascular (family) history and life style factors.

Study burden and risks

Participants will be asked to visit the NeuroImaging Center and a special testroom located on the UMCG. The first visit includes the behavioural part of the experiment that lasts approximately 75 minutes. To limit the burden, participants will be offered to take a 10 minute break halfway through the session. During the second visit, participants will be scanned in a 3 Tesla MRI scanner with rapidly alternating magnet gradients for about one hour. The selected scanning procedure is routinely used in fMRI research. Up till now, no substantial side effects have been reported. As the current study investigates the difference between regular depression and depression with CKD, both groups ought to be included in the study. The group of non-depressed patients with CKD is necessary create a contrast that captures the effects of depression with CKD by subtracting the effects of the somatic illness. Moreover, the group of healthy controls is included to be able to isolate the effects of regular depression. p[r

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for all groups are:
- Age > 18 yr
- signing informed consent form ;Depression in patients with chronic kidney disease (CKD):
- Predialysis patients or patients receiving either hemodialysis (HD) or peritoneal dialysis (PD) treatment
- Medical condition sufficient to participate as established by physician.
- Severity of depression established with BDI II, a score of 14 or more (mild-depression).;Non-depressed patients with CKD:
- Predialysis patients or patients receiving either HD or PD treatment
- Medical condition sufficient to participate as established by physician.
- No history of a previous or current depression
- Having a total BDI score lower than 14 ;Regular depression:
- Having a total BDI score of 14 or more. ;Healthy controls:
- Not fulfilling any of the above criteria

Exclusion criteria

General exclusion criteria:
I) Current neurological problems that may interfere with task performance, determined by questions
II) Use of drugs that may influence the task performance: We primarily aim at including

patients without any psychotrophic medication. If we find out during the study that there are not enough medication free patients to include in the study, we will try to match the participants in the non-CKD depression group on antidepressant and benzodiazepine use with participants in the CKD depression group.
III) Not being able to communicate in Dutch
IV) In case participants report concrete suïcidal plans in the MINI-SCAN interview a psychiatric advisor will be contacted by the interviewer. If the advisor confirms that the suicidal ideation is clinically relevant, the researcher will advise the participant to seek treatment and ask the participant permission to inform the participants psychiatrist or general practitioner (controls).The participant will be excluded from participating in the study. ;V) Due to the use of MRI scanning, the following additional criteria will apply:
The participants will have to fill out a detailed questionnaire covering safety aspects of the research in relation to the 3 Tesla magnetic field and the MRI environment.
These criteria are:
- MR incompatible implants in the body (such as ear prothesis or other metal implants)
- Any risk of having metal particles in the eyes due to manual work without proper eye protections
- Tattoos containing red pigments
- (Suspected) Pregnancy
- Claustrophobia
- The refusal to be informed of structural brain abnormalities that could be detected during the experiment ;Specific exclusion criteria per experimental group:
Depression in patients with CKD:
- Presence of any life-time and current psychiatric disorder, excluding nicotine dependence or history of alcohol dependence / abuse, any lifetime Anxiety Disorder and MDD in patients on HD as established by: I)Screening questions and eligible sections from MINI-scan interview
II)Questions on the use of psychotropic medication (antidepressive / anti-psychotic or sedative medication)
III)And, if possible, confirmation of this with information from the UMCG medical record ;Non-depressed patients with CKD:
-Presence of any life-time and current psychiatric disorder, excluding nicotine dependence or history of alcohol dependence / abuse, as established by the screening questions and eligible sections from the MINI-SCAN interview and a BDI score > 13.;Regular depression:
-Presence of any life time and current psychiatric disorder as diagnosed with the MINI scan, except MDD, nicotine dependence or history of alcohol dependence / abuse, any lifetime (not current) Anxiety Disorder (GAD) as established by:
I)Screening questions and eligible sections from the MINI-SCAN interview
II)Questions on the use of psychotropic medication (antidepressive / anti-psychotic or sedative medication)
III)And, if possible, confirmation of this with information from the UMCG medical record
-Any cardiovascular disease, (MI, heart failure, CVA, serious stenosis of a major vessel) or end-stage renal disease as indicated in a self report inventory. ;Healthy controls:
-Presence of any Life-time and current psychiatric disorder excluding nicotine dependence or history of alcohol dependence / abuse, as established by the screening questions and eligible sections from the MINI-SCAN interview and a BDI score > 9.
-Any cardiovascular disease, (MI, heart failure, CVA, serious stenosis of a major vessel) or renal disease as indicated in self-report inventory

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2012
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-06-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-09-2013
Application type:	Amendment

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	NL39351.042.12