Post MI Depression in the Picture; a fMRI study comparing depression following myocardial infarction and depression in a regular outpatient population

Published: 23-06-2010
Last updated: 03-05-2024

To compare cerebral activity patterns during emotional and cognitive processing among patients with post-MI depression and patients with regular depression.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON35007

Source
ToetsingOnline

Brief title
Post MI Depression in the Picture

Condition

- Myocardial disorders
- Mood disorders and disturbances NEC

Synonym
depression, depression after heart attack

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: cognition, Depression, emotion, myocardial infarction

Outcome measures

Primary outcome

Main study parameters are 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 occurring in the aftermath of a myocardial infarction (MI), experienced by 20-25% patients. Post-MI depression is consequential as it associated with a 2-2.5 fold increased mortality risk. Yet, attempts to treat post-MI depression and thereby improving cardiovascular prognosis have not been successful. We hypothesize that post-MI depression is different from regular depression, i.e. a major depressive disorder not following MI or another major somatic illness. Post-MI depression is often a first-ever depressive epsiode while regular major depression not following a MI or another major somatic illness has mostly a recurrent course. Also, the symptomatology differs. While regular depressions are characterized by cognitive symptoms, fatigue is prominently present in post-MI depression. In order to be able to discriminate both forms of depression and to better understand post MI depression, it is essential to study to what extent post MI depression differs from regular depression. In the future this may offer specific targets for the treatment of post-MI depression.

Study objective

To compare cerebral activity patterns during emotional and cognitive processing among patients with post-MI depression 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
3) Cognitive tasks to detect cognitive impairments which might confound results of
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 neuro-imaging center on two occasions. The first visit includes the behavioural part of the experiment that lasts approximately 90 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 post-MI depression both groups ought to be included in the study. The group of non-depressed MI patients is necessary create a contrast that captures the effects of post-MI depression by subtracting the effects of the myocardial infarction. Moreover, the group of healthy controls is included to be able to isolate the effects of regular depression.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
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
Incident post-MI depression:
-Meeting established criteria for recent (within 3 months before screening) MI: always documentation of increase of cardiac enzymes and either electro-cardial changes and/or chest pain.
Non-depressed MI patients:
-Meeting criteria for recent (3 months before screening) MI, as described above.
-No history of a previous or current depression
Regular depression:
- Meeting established criteria for an episode of major depressive disorder according to the DSM IV and severity as described above.
Healthy controls:
- Not fulfilling any of the above criteria.

Exclusion criteria

General exclusion criteria:
- I) Neurological problems (including epilepsy, and serious visual problems)
- II) Use of drugs that may influence the task performance:
We 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 only

include patients using SSRI*s and match on SSRI use with participants in the post MI depression group.
- III) Not being able to communicate in Dutch
- IV) In case participants report suïcidal ideation in the MINI-SCAN interview the participants psychiatrist or general practitioner (controls) will be informed and 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:;Incident post-MI depression
- Presence of any Life-time and current psychiatric disorder, excluding nicotine dependence, Generalized Anxiety Disorder (GAD) and MDD with post MI onset 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 MI patients:
-Presence of any Life-time and current psychiatric disorder, excluding nicotine dependence, as established by the screening questions and eligible sections from the MINI-SCAN interview and a BDI score < 9.;Regular depression:
-Presence of any life time and current psychiatric disorder as diagnosed with the MINI scan, except MDD, nicotine dependence, Generalized 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) as indicated in a self report inventory.;Healthy controls:
-Presence of any Life-time and current psychiatric disorder excluding nicotine dependence, 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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	15-12-2011
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	NL31753.042.10