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Netherlands Heart Foundation's Myocardial INfarction and Depression-Intervention Trial: effects of antidepressant treatment following myocardial infarction

Submission date
02/04/2012

Recruitment status
No longer recruiting

Registration date
22/05/2012

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Depression after myocardial infarction (heart attack) is associated with an increased risk of new cardiovascular events and mortality. The aim of MIND-IT was to find out whether offering antidepressant treatment improves cardiovascular prognosis in depressed myocardial infarction patients.

Who can participate?
Patients admitted for myocardial infarction to one of 10 hospitals in the Netherlands with a depressive episode during the first year after the myocardial infarction. In total of 331 patients participated.

What does the study involve?
The study investigates the effects of an antidepressant treatment strategy on depression and cardiovascular events in depressed myocardial infarction patients. Patients were randomly allocated into two groups: a study group and a usual care group. Patients in the study group were offered several types of antidepressant treatments from which they could choose
1. Mirtazapine versus placebo (dummy drug) on depression. If after 8 weeks there is no sufficient improvement in depression, open treatment with the antidepressant citalopram is offered.
2. Citalopram versus placebo on depression
The patients in the usual care received feedback about their depression status, but were told they were free to seek treatment for mood problems outside the study protocol. Hospital readmissions for cardiovascular reasons and mortality during the years following the treatment period were monitored.

What are the possible benefits and risks of participating?
Potential benefits are regular screening for depression after the myocardial infarction may

identify patients at increased risk of new cardiovascular events who would otherwise perhaps not be identified. Potential risks of participation in the trial for those in the placebo groups, is that depressed patients may be in need of antidepressants.

Where is the study run from?
Multiple sites in the Netherlands.

When is the study starting and how long is it expected to run for?
Recruitment of patients was between May 2000 and January 2003. The duration of trial for each patient was 6 months.

Who is funding the study?
The Netherlands Heart Foundation

Who is the main contact?
Prof. Dr. Peter de Jonge
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Contact information

Type(s)
Scientific

Contact name
Prof Peter de Jonge

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Additional identifiers

Study information

Scientific Title
Effects of antidepressant treatment following myocardial infarction: a randomized controlled trial

Acronym
MIND-IT

Study objectives
It is the aim of the Netherlands Heart Foundation's Myocardial INfarction and Depression-Intervention Trial (MIND-IT) to evaluate the influence of antidepressive treatment versus care-as-usual for post-myocardial infarction (MI) depression on cardiac prognosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Medical Ethical Commitee, University Medical Center Groningen, 1998, ref: METc: 98/11/191

Primary study design
Interventional

Study design
Multicenter single-blind randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Myocardial infarction and depression

Interventions
Patients in the intervention arm were offered several treatment options according to a strictly defined protocol:
First-choice treatment was double-blind placebo-controlled treatment with the selective noradrenaline reuptake inhibitor mirtazapine. In case of refusal or insufficient treatment response after 8 weeks, open treatment with the selective serotonin reuptake inhibitor (SSRI) citalopram was offered. Sufficient treatment response was defined as at least 50% reduction on the Hamilton Depression Rating Scale (HDRS) compared with baseline score or a HDRS score at 8 weeks of 49. Thus, patients who were initially treated with placebo and who did not improve within 8 weeks were subsequently treated with an SSRI.
The third option was 'tailored treatment' which was at the discretion of the clinical psychiatrist (e.g. SSRI, psychotherapy, etc.). Patients were scheduled to visit the psychiatrist on average once a month during the treatment period of 6 months.

Patients in the care as usual arm were not given feedback about their depression status, but were told that they were free to seek treatment for mood problems outside study procedures, which was monitored.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mirtazapine, citalopram

Primary outcome(s)
The occurrence of any significant cardiac event. Cardiac events included:
1. Cardiac death or hospital admission for documented non-fatal myocardial infarction
2. Myocardial ischaemia
3. Coronary revascularisation (coronary angioplasty or bypass surgery)
4. Heart failure or ventricular tachycardia occurring in the time between randomisation and 18 months postmyocardial infarction

Key secondary outcome(s)
Other cardiac-related hospital admissions (defined as admissions with an initial evaluation by a cardiologist or hospitalisations at the cardiology ward)

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Hospital admission for myocardial infarction, defined as: Documentation of an increase in cardiac enzymes and either electrocardiographic changes and/or chest pain (Enzyme changes: elevation of creatine kinase isoenzyme (CK-MB) (CK-MB _1_ ULN and CK-MB/CK ratio above the local normal limit) or in case CKMB is not available, elevation of total CK (total CK _2 _ ULN); electrocardiographic changes: new significant Q waves in at least 2 out of 12 leads or new R in V1 with R/S ratio _1;
Chest pain: _20 minutes of new or markedly increased chest pain)
2. Age more than or equal to18 years
3. Signed informed consent for study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Occurrence of MI while the patient was hospitalized for another reason, except for unstable angina pectoris
2. Lacking capability to participate in study procedures (ie, patients notable to communicate and patients not available for follow-up)
3. Any disease likely to influence short-term survival
4. Already receiving psychiatric treatment for depression
5. Participation in any clinical trial that might intervene with the study objectives and/or safety of the patient

Date of first enrolment
01/05/2000

Date of final enrolment

01/01/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
-

Study participating centre
Medical Centre Leeuwarden
-

Study participating centre
Medical Centre in Enschede
-

Study participating centre
Medical Centre in Heerenveen
-

Study participating centre
Medical Centre Drachten
-

Study participating centre
University Medical Centre Maastricht
-

Study participating centre
Medical Centre in Heerlen
-

Study participating centre
University Medical Centre Amsterdam
-

Study participating centre
Medical Centre in Amsterdam
-

Study participating centre
Medical Centre in Almere
-

Study participating centre
University Medical Centre Utrecht
-

Sponsor information

Organisation
The Netherlands Heart Foundation (Netherlands)

ROR
https://ror.org/05nxhgm70

Funder(s)

Funder type
Industry

Funder Name
Organon (Netherlands)

Funder Name
Lundbeck (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2007		Yes	No
Protocol article	study protocol	01/08/2002		Yes	No