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Interpersonal psychotherapy (IPT) and citalopram for depression in coronary artery disease

Submission date	Recruitment status	[ ] Prospectively registered
17/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/02/2009	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-50397

Study information

Scientific Title
A randomised, controlled trial of interpersonal psychotherapy (IPT) and citalopram for depression in coronary artery disease

Acronym
CREATE

Study objectives
1. To determine whether 12 weeks of treatment with IPT is more effective than 12 weeks of clinical management in reducing depressive symptoms
2. To determine if 12 weeks of citalopram is more effective than placebo in reducing depressive symptoms
3. To report data on the tolerability and the safety of each treatment in comparison to the control condition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institut de Cardiologie de Montréal Ethics Committee gave approval on the 30th July 2001.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major depression

Interventions

Participants are randomly assigned to receive 12 weekly IPT sessions or 12 weekly sessions of standardized clinical management (CM). Patients are also randomly assigned to receive 20-40 mg per day of citalopram or pill-placebo. This results in four groups:
Group 1 receives IPT plus CM and citalopram
Group 2 receives IPT plus CM and placebo
Group 3 receives CM and citalopram
Group 4 receives CM and placebo

Patients in all 4 groups take part in weekly, individual CM sessions involving a brief structured review of side effects and progress that lasts 15 to 20 minutes. These sessions are administered by the IPT therapists, who have been trained to evaluate side effects and cardiac symptoms, and are supervised by the site principal investigators. In groups 1 and 2, IPT is administered over 40 to 60 minutes on a weekly basis by a certified IPT therapist who follows the treatment manual developed by Klerman et al. The intervention was slightly adapted to meet the needs of depressed CAD patients, including a 12 week duration of therapy instead of the usual 16 weeks to decrease the time maintaining patients on a placebo, and also to decrease the study burden on patients in order to maximize the rate of treatment completion. IPT sessions immediately follow structured CM. To facilitate participation in the intended 12 IPT sessions, up to 4 sessions may be conducted by telephone if needed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Citalopram

Primary outcome measure
The 24-item HAM-D administered centrally by phone at baseline, 6- and 12-weeks.

Secondary outcome measures
The self-report Beck Depression Inventory (BDI-II) administered at baseline, 6- and 12-weeks.

Overall study start date
01/04/2002

Completion date
01/04/2006

Eligibility

Key inclusion criteria
Persons of either sex in age groups: 18 years and above.
1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of current major depressive episode based on the Structured Clinical Interview for Depression (SCID) with at least 4 weeks duration
2. Baseline score greater than 19 on the centralized, telephone-administered 24-item, Hamilton Depression Rating Scale (HAM-D)

3. Evidence of coronary artery disease (CAD) based on hospital chart evidence of a previous hospitalization for acute myocardial infarction, or coronary angiographic evidence of greater than 50% blockage in at least one major coronary artery, or prior revascularization
4. Stable CAD based on physicians clinical judgement
5. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Less than 18 years of age
2. Coronary bypass surgery planned during the next 4 months
3. Canadian Cardiovascular Society Angina Class (CCS) = 4
4. SCID documented bipolar disorder, major depression with psychotic features or evidence of substance abuse or dependency during the previous 12 months
5. Serious suicide or risk based on clinical judgment
6. Use of anti-depressants, lithium or anti-convulsants for mood disorder
7. Currently undergoing any form of psychotherapy
8. Absence of response to a previous adequate trial of citalopram or IPT
9. Two previous unsuccessful trials of treatment for depression for the index episode
10. Lifetime history of early termination (less than 8 weeks) of citalopram because of adverse events or side-effects
11. Lifetime history of early termination (less than 8 weeks) of two other selective serotonin reuptake inhibitor (SSRI) antidepressants (paroxetine, fluoxetine, fluvoxamine, sertraline) because of adverse events or side-effects
12. Significant cognitive problems (Mini-Mental Status Exam [MMSE] less than 24)
13. Depression due to a general medical condition based on clinical judgment
14. Participation in other trials
15. Inability to speak French or English
16. Investigators judgment that a patient is unable or unwilling to comply with the study regimen

Date of first enrolment
01/04/2002

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Canada

Study participating centre
Chief
Montreal, Quebec
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Sponsor information

Organisation
Montreal Heart Institute Research Center (Canada)

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Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-50397)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	design and rationale	01/01/2006		Yes	No
Results article	results	24/01/2007		Yes	No
Results article	biomarker sub-study results	01/01/2009		Yes	No