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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
17/08/2005				
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
17/08/2005		[X] Results		
Last Edited		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

#### Contact name

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#### Contact details

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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, fluoxamine, 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 Canada H2L 4M1

# Sponsor information

#### Organisation

Montreal Heart Institute Research Center (Canada)

#### Sponsor details

5000 est, rue Bélanger Montreal, Quebec Canada H1T 1C8 +1 514 376 3330 ext. 3515 jacqueline.loiselle@icm-mhi.org

#### 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