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Zyban as an effective smoking cessation aid for patients following acute coronary syndrome (ACS): The ZESCA trial

Submission date 29/07/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/07/2005	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Circulatory System	

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
NCT00689611

Secondary identifying numbers
MCT-64989

Study information

Scientific Title
Zyban as an effective smoking cessation aid for patients following acute coronary syndrome (ACS): a randomised controlled trial

Acronym
ZESCA

Study objectives
Nicotine dependence in patients with a recent enzyme-positive acute coronary syndrome:
1. To examine the impact of sustained-release bupropion on smoking abstinence rates at one year following an enzyme-positive acute coronary syndrome
2. To examine the safety of sustained-release bupropion in patients following an ACS

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, Jewish General Hospital, Montreal, 24/01/2005

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
Sustained-release bupropion versus placebo.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Smoking abstinence rates at 12 months post-ACS

Secondary outcome measures
1. Cumulative side effects and safety of bupropion at 9 weeks
2. Composite clinical events (unstable angina, myocardial infarction [MI], seizure, death)

Overall study start date
01/09/2005

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Age: greater than or equal to 18 years
2. Active smoker (greater than or equal to 10 cigarettes per day, on average) for the past year
3. Suffered an ACS and planned hospitalization of greater than or equal to 48 hours
ACS is defined as positive Troponin T, Troponin I, or CK-MB levels and greater than or equal to one of the following:
3.1. Ischaemic symptoms (i.e. typical chest pain) for at least 20 minutes
3.2. Electrocardiogram (ECG) changes indicative of ischemia (ST-segment elevation or depression)
3.3. Development of pathological Q waves on the ECG
Note: If patient is to undergo percutaneous coronary intervention (PCI) and/or coronary artery bypass graft surgery (CABG), they are still eligible to be enrolled.
4. Motivated to quit smoking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500

Key exclusion criteria
1. Current seizure disorder, history of seizures, or predisposition to seizures (e.g. history of brain tumour, severe head trauma, or stroke)
2. Current use of medications that lower seizure threshold e.g. amantadine, anti-depressants, anti-malarials, anti-psychotics, levodopa, lithium, quinalone antibiotics, ritonavir, systemic steroids, theophyllin, type 1C antiarrhythmics (e.g. encainide, flecainide, propafenone)
3. History of anorexia nervosa or bulimia
4. Current use of Wellbutrin or any other medications that contain bupropion
5. Pregnancy or lactation

Date of first enrolment
01/09/2005

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Canada

Study participating centre
McGill University
Montreal, Quebec
Canada
H3T 1E2

Sponsor information

Organisation
Sir Mortimer B Davis Jewish General Hospital (Canada)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.cihr-irsc.gc.ca

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Basic results				No	No
Results article	results	01/03/2014	11/04/2019	Yes	No

Results article	results	01/03/2014	11/04/2019	Yes	No