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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 guit 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

3755 Côte Ste Catherine Montreal, Quebec Canada H3T 1E2 +1 (0)514 340 8222 meisenberg@epid.jgh.mcgill.ca

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