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# A Multi-center Randomized Double-Blind Trial Comparing Rosiglitazone to Placebo for the Prevention of Atherosclerosis Progression after Coronary Bypass Surgery in Diabetic Patients

**Submission date**
29/01/2005

**Registration date**
21/02/2005

**Last Edited**
28/01/2019

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Circulatory System

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

**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**
NCT00169832

### Secondary identifying numbers
49653/416

# Study information

### Scientific Title
Cardiometabolic effects of rosiglitazone in patients with type 2 diabetes and coronary artery bypass grafts: A randomized placebo-controlled clinical trial

### Acronym
VeIn-Coronary aTherOsclerosis and Rosiglitazone after bypass surgerY. The VICTORY Trial.

### Study objectives
Hypotheses:
1. Rosiglitazone in diabetic patients with previous coronary bypass surgery may prevent or slow the progression of atherosclerosis in saphenous vein grafts (SVGs) and native coronary arteries
2. Rosiglitazone has favorable effects on adipose tissue distribution variables as well as on thrombosis, pro-inflammatory, and lipid profiles in diabetic patients after coronary bypass artery surgery
3. Rosiglitazone therapy influences favorably metabolism and clinical outcomes in diabetic patients after coronary artery bypass surgery

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Multi-centre

### Study setting(s)
Not specified

### Study type(s)
Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied
Diabetes

### Interventions

A multi-center randomized double-blind trial comparing rosiglitazone to placebo.

At baseline, patients undergo
1. Angiography and intravascular ultrasound examinations
2. Abdominal fat distribution (computed tomography [CT] scan) and body composition (dual energy X-ray absorptiometry [DEXA])
3. Blood tests
4. Exercise test
5. Holter monitoring

After 12 months follow-up, all tests are repeated.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Rosiglitazone

## Primary outcome measure
The primary endpoint of the study will be the change (12-month intravascular ultrasound [IVUS] Baseline IVUS) in plaque volume in a segment of at least 40 mm in one SVG as measured by IVUS.

## Secondary outcome measures
IVUS:
1. The change in plaque volume from baseline to 12 month follow-up in a segment of anastomosed coronary artery of at least 20 mm
2. The changes from baseline to 12-month follow-up in lumen volume and in total vessel volume in the ≥40 mm SVG segment and in the ≥20 mm coronary segment
3. The changes from baseline to 12-month follow-up in lumen area, plaque area, and total vessel area in the ≥40 mm SVG segment and in the ≥20 mm coronary segment
4. The changes from baseline to 12-month follow-up in qualitative plaque characterization in the ≥40 mm SVG segment and in the ≥20 mm coronary segment
5. The proportion of patients showing atherosclerosis changes (progression/regression)
6. The proportion of patients showing atherosclerosis changes 'concordance', i.e. progression in SVG segment and coronary segment and atherosclerosis 'discordance', i.e. progression, stabilization or regression noted in one of the analyzed segment not found in the other analyzed segment

Angiography:
1. The proportion of patients showing new occlusions in native coronary arteries or SVGs
2. The changes in reference and minimum lumen diameters of the SVG as assessed by quantitative coronary angiography (QCA)
3. The per-patient percentage of initially patent SVGs that had significant progression of atherosclerosis at the site of greatest change at follow-up

Metabolic risk factors:
Changes from baseline to 6 and 12 months of indices for comprehensive lipid, thrombosis and pro-inflammatory profiles as well as glucose-insulin homeostasis, microalbuminuria, adhesion

molecules, adipokines, and other markers relevant to the evaluation and management of cardiovascular disease risk

Body composition and distribution parameters:
1. Changes in abdominal areas and volumes of adipose tissue as well as mid-thigh areas of adipose tissue and muscle attenuations assessed by computed tomography (CT) from baseline to 6 and 12 months
2. Changes in body composition assessed by DEXA from baseline to 6 and 12 months and bioelectrical impedance analysis (BIA) from baseline to 2, 4, 6 and 12 months
3. Changes in body weight, waist circumference and body mass index (BMI) will be evaluated from baseline to 2, 4, 6, 8, 10 and 12 months

Clinical outcomes:
1. The recording of clinical laboratory parameters, physical examinations, vital signs (blood pressure and heart rate), electrocardiograms, concomitant medication, and adverse events will assess patients safety
2. Presence of any of the following: death, myocardial infarction (MI), transient ischemic attack (TIA), stroke, hospitalization, and ischemia-driven interventions (percutaneous coronary intervention [PCI]/CABG) will be recorded
3. Fluid retention will be evaluated by BIA

### Overall study start date
01/04/2003

### Completion date
30/06/2006

## Eligibility

### Key inclusion criteria
Stable diabetic patients (HbA1c inferior or equal to 9.0%) with previous coronary bypass surgery (1-10 years) and a suitable 40 mm segment in a vein graft and a 20 mm segment in native coronary artery.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
280

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment

01/04/2003

**Date of final enrolment**
30/06/2006

# Locations

**Countries of recruitment**
Canada

**Study participating centre**
**Laval Hospital**
Québec
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# Sponsor information

**Organisation**
Laval Hospital Research Center (Canada)

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**Sponsor type**
Hospital/treatment centre

# Funder(s)

**Funder type**
Industry

**Funder Name**
This is an investigator-initiated-trial which is funded by an unrestricted grant from GlaxoSmithKline

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2010 | 28/01/2019 | Yes | No |