

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/02/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/01/2019	Condition category Circulatory System	<input type="checkbox"/> 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

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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