

Diabetes REduction Approaches with ramipril and rosiglitazone Medications

Submission date

26/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

26/09/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

21/12/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Hertz G Gerstein

Contact details

McMaster University
1200 Main Street West
Room 3V38
Hamilton
Canada
L8N 3Z5
+1 905-521-2100 (73371)
gerstein@mcmaster.ca

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00095654

Protocol serial number

MCT-41548

Study information

Scientific Title

A large, international, multi-centre, randomised double-blind controlled trial designed to determine if treatment with either ramipril and/or rosiglitazone will prevent or reduce the incidence of diabetes in people with impaired glucose tolerance (IGT) or impaired fasting glucose (IFG)

Acronym

DREAM

Study objectives

Does the addition of either ramipril (up to 15 mg/day) or rosiglitazone (8 mg/day) prevent the composite outcome of either type 2 diabetes or all-cause mortality in non-diabetic people with impaired glucose tolerance (IGT) or impaired fasting glucose (IFG)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Board of McMaster University, Hamilton, Ontario gave approval on the 21st February 2001.

Study design

International multicentre randomised double-blind controlled 2 x 2 factorial trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Impaired glucose tolerance (IGT) and isolated impaired fasting glucose (IFG)

Interventions

Group 1: ramipril titrated to 15 mg/day or highest tolerated dose for a minimum of 3 and up to 5 years

Group 2: placebo titrated to 15 mg/day or highest tolerated dose for a minimum of 3 and up to 5 years

Group 3: rosiglitazone titrated to 8 mg

Group 4: placebo titrated to 8 mg

Trial details received: 12 Sept 2005

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ramipril, rosiglitazone

Primary outcome(s)

Diabetes mellitus or death (any cause) determined within 5 years.

Key secondary outcome(s)

1. Q wave MI
2. Non-Q wave MI
3. MI and no electrocardiogram (ECG) change
4. Ischaemic stroke
5. Haemorrhagic stroke
6. Uncertain stroke
7. Cardiovascular (CV) death
8. Heart failure
9. CV revascularisation
10. Angina
11. Ventricular tachyarrhythmia
12. Creatinine clearance
13. Albuminuria progression determined within 5 years

Completion date

31/10/2006

Eligibility

Key inclusion criteria

1. Women and men of any ethnic background and age greater than or equal to 30 years
2. A fasting plasma glucose value less than 7 mmol/l and a two-hour plasma glucose 7.8 - 11.0 mmol/l after a 75 g oral glucose tolerance test (OGTT) or fasting plasma glucose 6.1 - 6.9 mmol/l and a two-hour plasma glucose less than 7.8 mmol/l

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Current use of an angiotensive converting enzyme (ACE) inhibitor, thiazolidinedione
2. Known hypersensitivity to ACE inhibitors or use of systemic glucocorticoids or niacin
3. Cardiovascular disease (previous myocardial infarction (MI), stroke, angina, congestive heart failure or previous coronary or peripheral angioplasty or bypass, or uncontrolled hypertension)
4. Previous diagnosis of diabetes, renal or hepatic disease, disease that affects glucose tolerance or major psychiatric disorder

Date of first enrolment

01/10/2000

Date of final enrolment

31/10/2006

Locations

Countries of recruitment

Canada

Study participating centre

McMaster University

Hamilton

Canada

L8N 3Z5

Sponsor information

Organisation

McMaster University (Canada)

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-41548)

Funder Name

Sanofi-Aventis

Funder Name

King Pharmaceuticals

Alternative Name(s)

King Pharmaceuticals, Inc.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

GlaxoSmithKline

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2006		Yes	No
Results article	results	01/05/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes