ISRCTN61497824 https://doi.org/10.1186/ISRCTN61497824

Diabetes REduction Approaches with ramipril and rosiglitazone Medications

Submission date	Recruitment status
26/09/2005	No longer recruiting
Registration date	**Overall study status**
26/09/2005	Completed
Last Edited	**Condition category**
21/12/2009	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.dtu.ox.ac.uk/index.html?maindoc=/4-T/

Contact information

Type(s)
Scientific

Contact name
Dr Hertzel 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00095654

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2000

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

Age group
Adult

Sex
Both

Target number of participants
5000

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)

Sponsor details
Office of the Associate Dean
Research
McMaster University
Faculty of Health Sciences
1200 Main St. W., Room HSC-3N8

Hamilton
Canada
L8N 3Z5

Sponsor type
University/education

Website
http://www.mcmaster.ca/

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., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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	01/10/2006		Yes	No
Results article	results	01/05/2008		Yes	No
Results article	results	01/03/2010		Yes	No