ISRCTN05215453 https://doi.org/10.1186/ISRCTN05215453

Effect of rosiglitazone, compared to sulphonylurea, on endothelial function in Chinese patients with type two diabetes

Submission date 14/11/2006	**Recruitment status** No longer recruiting
Registration date 29/11/2006	**Overall study status** Completed
Last Edited 20/11/2007	**Condition category** 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

Contact information

Type(s)
Scientific

Contact name
Prof Karen Lam

Contact details
The University of Hong Kong
Queen Mary Hospital
Pokfulam
Hong Kong
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HKCTR-1

Study information

Scientific Title

Study objectives
1. Rosiglitazone improves endothelial function independent of its effect on glycemic control
2. Rosiglitazone affects soluble receptor of advanced glycation end products independent of its effect on glycemic control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board of the University of Hong Kong /Hospital Authority Hong Kong West Cluster on the 19th March 2004 (ref: UW 04-045 T/367).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes

Interventions
Patients were randomised to receive add-on therapy with either rosiglitazone 4 mg or glibenclamide 5 mg (or gliclazide 80 mg) daily while keeping the doses of their usual anti-diabetic agents constant. After four weeks, the doses of the add-on therapy were doubled in subjects with fasting blood glucose level greater than 8.0 mmol/l and without symptomatic or asymptomatic hypoglycemia defined as blood glucose level less than 3.0 mmol/l. The dosages of all anti-diabetic agents were then kept constant for another 20 weeks.

There was no washout period and all study medications were administered orally.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rosiglitazone and sulphonylurea

Primary outcome measure
Changes in endothelial function in patients with type two diabetes

Secondary outcome measures
1. Changes in blood pressure and metabolic parameters such as C-reactive protein.
2. Changes in serum soluble Receptor for Advanced Glycation End products (sRAGE) and advanced glycation end products.

Overall study start date
23/03/2004

Completion date
01/04/2006

Eligibility

Key inclusion criteria
1. Chinese men and women aged 30 to 70 years
2. Type two diabetes (defined by the World Health Organization [WHO] criteria) diagnosed after 30 years of age
3. On diet with/without sulphonylurea (less than or equal to half-maximum dose) with/without metformin for at least six months
4. No change in anti-diabetic, lipid lowering and anti-hypertensive in preceding 12 weeks
5. Body Mass Index (BMI) more than or equal to 23 and less than or equal to 35 kg/m^2
6. Systolic blood pressure less than or equal to 160 mmHg and diastolic blood pressure less than or equal to 90 mmHg
7. HbA1c levels between 7.5 and 10.5% inclusively (normal less than or equal to 6.1%) on at least two occasions in the past three months
8. Female patients must be post-menopausal (i.e. more than six months without menstrual period), surgically sterilised, or using hormonal contraceptives or intrauterine devices

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68

Key exclusion criteria

1. Pregnancy or lactation
2. Any clinically significant abnormality identified on the screening physical examination, laboratory tests, or electrocardiogram which, in the judgement of the investigator, would preclude the safe completion of the study
3. Use of anti-diabetic drugs other than metformin or sulphonylurea within 12 weeks
4. Use of any investigational drug within 30 days or five half-lives (whichever is longer) preceding the first dose of study medication
5. Patients with a documented history of significant hypersensitivity to any drugs including thiazolidinedione and sulphonylurea (e.g., difficulty in swallowing or breathing, or tachycardia)
6. Active alcohol or drug abuse within the last six months
7. Presence of clinically significant renal or hepatic disease:
7.1. Serum creatinine above Upper Normal Range (UNR) (creatinine more than 128 umol/L for males and more than 107 umol/L for females)
7.2. Proteinuria more than 1 gm/day
7.3. Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), total bilirubin, or alkaline phosphatase more than two times above UNR
8. Significant anaemia (haemoglobin less than 11 g/dl for males or less than 10 g/dl for females)
9. Patients with haemoglobinopathies
10. Leukocyte count less than 3.0 x 10^9/L or platelet count less than 120 x 10^9/L
11. Patients with severe angina, coronary insufficiency, heart failure (New York Heart Association [NYHA] class III or IV), or history of cardiovascular event in the past six months
12. Patients with electrocardiographic evidence of left ventricular hypertrophy based upon the maximal voltage of Sv1 plus the maximal voltage of Rv5 or Rv6 more than 3.5 mV and ST-T segment changes
13. Symptomatic diabetic neuropathy of sufficient severity to require treatment for control of symptoms (e.g. painful peripheral neuropathy, symptomatic orthostatic hypotension, urinary retention, pedal ulcers, gastric stasis, etc.)
14. Patients with history of psychiatric illness

Date of first enrolment
23/03/2004

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Hong Kong

Study participating centre
The University of Hong Kong
Pokfulam
Hong Kong
-

Sponsor information

Organisation
Hong Kong University Research Committee (Hong Kong)

Sponsor details
7/F., Shui On Centre
6-8 Harbour Road
Wanchai
Hong Kong
-

Sponsor type
Research organisation

ROR
https://ror.org/02zhqgq86

Funder(s)

Funder type
University/education

Funder Name
Hong Kong University Research Committee (Hong Kong) (project no. HKU 7637/05M)

Funder Name
HK Innovation and Technology Support Programme (Hong Kong) (project no. ITS/048/03)

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	01/09/2007		Yes	No