

A randomized, open-labelled, parallel, comparative study of the efficacy and tolerability of rosuvastatin in low-density lipoprotein-cholesterol reduction using different dosing regimens of 5 mg daily, 10 mg daily and 10 mg on alternate days in Hong Kong Chinese type 2 diabetic patients

Submission date 13/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/03/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/03/2006	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

Alternate day dosing of rosuvastatin 10 mg is comparable to daily dosing of rosuvastatin 5 mg

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study protocol, informed consent documents, any addenda or amendments have been reviewed and approved jointly by the Chinese University of Hong Kong, New Territories and the East Cluster Clinical Research Ethics Committee, reference number CRE-2005.095-T

Study design

Randomized, open-labelled, parallel-group study using rosuvastatin 5 mg daily, 10 mg daily or 10 mg on alternate days in patients with Low-Density Lipoprotein (LDL) Cholesterol ≥ 2.6 mmol/l after following a standard lipid lowering diet

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dyslipidaemia

Interventions

Drug intervention: rosuvastatin 5 mg daily or 10 mg daily or 10 mg on alternate days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rosuvastatin

Primary outcome(s)

Percentage change of LDL-Cholesterol at 12 weeks and 24 weeks from baseline parameter in the three study arms using different dosing regimes of rosuvastatin

Key secondary outcome(s))

1. Percentage change of total cholesterol, triglyceride levels and High-Density Lipoprotein-Cholesterol (HDL-C) at 12 weeks and 24 weeks from baseline parameters in the three study arms using different dosing regimes of rosuvastatin
2. Effects on glycemic control as determined by fasting glucose and HbA1c at 12 weeks and 24 weeks
3. Effects on insulin resistance as determined by Homeostasis Model Assessment (HOMA) at 12 and 24 weeks
4. Effects on urinary albumin excretion and creatinine clearance as assessed at 12 and 24 weeks

Completion date

18/12/2006

Eligibility

Key inclusion criteria

1. Type 2 diabetic patients 18 to 75 years of age
2. Treated with diet alone, oral hypoglycemic agents and/or insulin
3. LDL-Cholesterol ≥ 2.6 mmol/l
4. Dyslipidaemia persisting after diet control for eight weeks or more
5. Alcohol consumption < 50 g/day
6. Not on treatment with drugs known to interfere with glucose tolerance or drugs that have a major effect on lipid metabolism e.g. thiazide diuretics and beta-blockers
7. Good compliance to diet and drugs
8. HbA1c $< 9\%$ (glucosylated haemoglobin $< 9\%$)
9. Blood pressure $< 160/95$ mmHg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Significantly impaired renal function (plasma creatinine > 150 micromol)
2. Impaired liver function (Serum Glutamic Pyruvic Transaminase [SGPT] or alanine aminotransferase [ALT] twice the upper limit of normal)
3. Secondary dyslipidaemia, diabetic dyslipidaemia
4. Pregnant women or those planning a pregnancy
5. Lactation
6. Progressive fatal disease
7. History of drug or alcohol abuse

8. History of hypersensitivity to study medication or drugs with a similar chemical structure
9. Likelihood of requiring treatment during the study period with the following drugs:
cyclosporine, erythromycin

Date of first enrolment

18/06/2005

Date of final enrolment

18/12/2006

Locations

Countries of recruitment

Hong Kong

Study participating centre

Flat 8A

Shatin, New Territories

Hong Kong

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Sponsor information

Organisation

Chinese University of Hong Kong

ROR

<https://ror.org/00t33hh48>

Funder(s)

Funder type

University/education

Funder Name

Chinese University of Hong Kong (investigator-initiated study)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration