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# A randomized, open-labelled, parallel, comparative study of the efficacy and tolerability of rosuvastatin in low-density lipoprotein-cholestrol 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

**Registration date**
01/03/2006

**Last Edited**
01/03/2006

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Francis C.C. Chow

**Contact details**
Flat 8A
Block B
Staff Quarters
Prince of Wales Hospital
Shatin, New Territories
Hong Kong
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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### 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
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 measure
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

### Secondary outcome measures
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

### Overall study start date
18/06/2005

### 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

### Age group
Adult

### Lower age limit

18 Years

### Sex
Both

### Target number of participants
120

### 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

### Sponsor details

Flat 8A
Block B
Staff Quarters
Prince of Wales Hospital
Shatin, New Territories
Hong Kong
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### Sponsor type
University/education

### ROR
https://ror.org/00t33hh48

## Funder(s)

### Funder type
University/education

### Funder Name
Chinese University of Hong Kong (investigator-initiated study)

## 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