

A randomized, double blind, placebo-controlled trial on the effect of rosiglitazone in reversing newly diagnosed type 2 diabetes to non-diabetic status

Submission date 11/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/03/2006	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Study objectives

Rosiglitazone will be effective in reversing newly diagnosed mild diabetes to non-diabetic status

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-2003.111-T

Study design

Randomized, double-blind, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus (type 2)

Interventions

Primary intervention: rosiglitazone versus placebo for 52 weeks

Secondary intervention: standard lifestyle modification advice

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rosiglitazone

Primary outcome(s)

Glycaemic status as assessed by 75 g OGTT at 52 weeks

Key secondary outcome(s)

1. Change of insulin resistance and insulin reserve as assessed by Homeostasis Model Assessment (HOMA) at 52 weeks
2. Cardiovascular risk factors assessed at 52 weeks
3. Treatment effect 13 weeks after treatment stopped

Completion date

25/01/2006

Eligibility

Key inclusion criteria

1. Type 2 diabetic patients above 18 years of age
2. Newly diagnosed diabetes within one year with HbA1c <7% at the time of entry to the study
3. No history of exposure to any anti-diabetic medications except diet control or insulin during period of gestational diabetes
4. Alcohol consumption less than 50 g/day

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 with plasma creatinine >200 mmol/l
2. Known case of liver cirrhosis (Child's B grading or above) or significantly impaired liver function (alanine aminotransferase [ALT] or aspartate aminotransferase [AST], greater than two times the upper limit of normal)
3. Congestive heart failure of class III or IV by the New York Heart Association classification (NYHA)
4. Progressive fatal disease
5. History of drug or alcohol abuse
6. History of hypersensitivity to study medication or drugs with similar chemical structure to rosiglitazone
7. Pregnant women or those planning a pregnancy
8. Lactation
9. Known severe non-compliance to medication or any factor, which will affect the completion of the study as judged by the investigator
10. Need of any medication, which will affect interpretation of Oral Glucose Tolerance Test (OGTT) such as regular oral steroid or episodic high dose steroid

Date of first enrolment

09/09/2003

Date of final enrolment

25/01/2006

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

Funder Name
(investigator-initiated study)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration