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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

Registration date
28/02/2006

Last Edited
01/03/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] 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

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Additional identifiers

Protocol serial number
N/A

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