ISRCTN76036162 https://doi.org/10.1186/ISRCTN76036162

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	Recruitment status	[_] Prospectively registered
11/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/03/2006	Urological and Genital Diseases	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Glycaemic status as assessed by 75 g OGTT at 52 weeks

Secondary outcome measures
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

Overall study start date
09/09/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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

Sponsor details
Flat 8A
Block B
Staff Quarters
Prince of Wales Hospital
Shatin, New Territories
Hong Kong
-

Sponsor type
University/education

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

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