

The use of rosiglitazone or bedtime insulin in the treatment of conventional oral anti-diabetic drug failure: a one-year randomized clinical trial

Submission date

28/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/04/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

24/09/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

To evaluate the efficacy and tolerability of rosiglitazone in the treatment of secondary oral anti-diabetic drug (OAD) failure and its direct comparisons against bedtime insulin

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the AH Nethersole Hospital Ethics Committee, December 1999

Study design

Randomized open-labelled comparing two standard therapies

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 diabetic patients with conventional OAD failure

Interventions

Add-on with either rosiglitazone or nocte insulin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rosiglitazone, insulin

Primary outcome(s)

Glycaemic improvement

Key secondary outcome(s)

1. Lipid and blood pressure (BP) changes
2. Tolerability

Completion date

31/12/2001

Eligibility**Key inclusion criteria**

Chinese type 2 diabetic patients with conventional OAD failure

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Type 1 diabetes

Date of first enrolment

10/01/2000

Date of final enrolment

31/12/2001

Locations**Countries of recruitment**

Hong Kong

Study participating centre**Block J**

New Territories

Hong Kong

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Sponsor information**Organisation**

AH Nethersole Hospital, Department Research Fund (Hong Kong)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Self-funded - Departmental Research Fund

Funder Name

AH Nethersole Hospital

Funder Name

Department of Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2006		Yes	No