

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Glycaemic improvement

Secondary outcome measures

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

Overall study start date

10/01/2000

Completion date

31/12/2001

Eligibility

Key inclusion criteria

Chinese type 2 diabetic patients with conventional OAD failure

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

110

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)

Sponsor details

Block J

6th Floor

AH Nethersole Hospital

Department of Medicine

Tai Po

New Territories

Hong Kong

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Sponsor type

Hospital/treatment centre

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

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

Study outputs

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