

# 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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Tai Po

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Hong Kong

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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?
<a href="#">Results article</a>	results	01/09/2006		Yes	No