

# The safety and efficacy of CCX140-B in subjects with type 2 diabetes

**Submission date**  
15/12/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
11/02/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
20/02/2019

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

**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**  
NCT01028963

**Secondary identifying numbers**  
CL004\_140

# Study information

## Scientific Title

A randomised, double-blind, placebo- and active-controlled, phase 2 study to evaluate the safety and efficacy of CCX140-B in subjects with type 2 diabetes mellitus

## Study objectives

CCX140-B is safe and well tolerated in subjects with type 2 diabetes mellitus based on subject incidence of adverse events.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Australia: Bellbery Ethics Committee, 08/12/2009, ref: C196/09

Pending as of 21/12/2009:

New Zealand

Czech Republic

Germany

Hungary

## Study design

Randomised double-blind placebo- and active-controlled phase II study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

## Interventions

1. Placebo capsule, once daily
2. Pioglitazone 30 mg tablet once daily
3. CCX140-B capsule, once daily

Total duration of treatment: 28 days

Total duration of follow-up: 28 days

## **Intervention Type**

Drug

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

CCX140-B

## **Primary outcome measure**

Subject incidence of adverse events as measured by subject incidence of adverse events over 28-day dosing period.

## **Secondary outcome measures**

Evaluate the effectiveness of CCX140-B versus placebo as measured by fasting plasma glucose concentration, measured at day 29.

## **Overall study start date**

01/01/2010

## **Completion date**

30/08/2010

# **Eligibility**

## **Key inclusion criteria**

1. Male, post-menopausal (at least 2 years) or surgically sterile female subjects, aged 18 - 70 years inclusive, with type 2 diabetes mellitus
2. Must have a body mass index greater than or equal to 25 and less than 45 kg/m<sup>2</sup>, but if body mass index is greater than or equal to 25 and less than 28 kg/m<sup>2</sup>, then waist circumference must be greater than 94 cm for men and greater than 80 cm for women
3. Must be on a stable dose of metformin for at least 8 weeks prior to randomisation
4. Haemoglobin A1c (HbA1c) of 6.5 to 10.0% inclusive and fasting plasma glucose 135 to 270 mg/dL inclusive at screening

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

**Target number of participants**

140

**Key exclusion criteria**

1. Type 1 diabetes mellitus or history of diabetic ketoacidosis
2. Received insulin treatment within 12 weeks of randomisation
3. Received chronic (more than 7 days) systemic glucocorticoid treatment within 12 weeks of randomisation
4. Received sulfonylurea, thiazolidinedione, exenatide, or any other glucose lowering treatment (other than metformin) within 8 weeks of randomisation
5. Symptomatic congestive heart failure requiring prescription medication, clinically evident peripheral oedema, poorly-controlled hypertension (systolic blood pressure greater than 160 or diastolic blood pressure greater than 100), history of unstable angina, myocardial infarction or stroke within 6 months of randomisation, or chronic renal failure
6. History or presence of drug-induced myopathy, drug-induced creatine kinase elevation, or leukopaenia (white blood cell [WBC] count less than  $3.5 \times 10^9/L$ )
7. History or presence of any form of cancer within the 5 years prior to randomisation, with the exception of excised basal cell or squamous cell carcinoma of the skin, or cervical carcinoma in situ or breast carcinoma in situ that has been excised or resected completely and is without evidence of local recurrence or metastasis
8. Fasting serum triglyceride greater than 400 mg/dL

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

30/08/2010

**Locations****Countries of recruitment**

Australia

United States of America

**Study participating centre**

850 Maude Avenue

California

United States of America

94043

**Sponsor information****Organisation**

ChemoCentryx, Inc. (USA)

**Sponsor details**

850 Maude Avenue  
Mountain View  
California  
United States of America  
94043

**Sponsor type**

Industry

**Website**

<http://www.chemocentryx.com/>

**ROR**

<https://ror.org/04gp12571>

**Funder(s)****Funder type**

Industry

**Funder Name**

ChemoCentryx, Inc. (USA)

**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		20/02/2019	Yes	No