

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

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| Submission date 15/12/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 11/02/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 20/02/2019 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

ClinicalTrials.gov (NCT)
NCT01028963

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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/m², but if body mass index is greater than or equal to 25 and less than 28 kg/m², 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

ChemoCentryx, Inc. (USA)

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 | | 20/02/2019 | Yes | No |