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

Submission date	Recruitment status	[_] Prospectively registered
15/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2019	Nutritional, Metabolic, Endocrine	

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^2, but if body mass index is greater than or equal to 25 and less than 28 kg/m^2, then waist circumference must be greater then 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 x 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?
Results article	results		20/02/2019	Yes	No