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Clinical trial to evaluate the safety and efficacy of CCX140-B in diabetic nephropathy

Submission date
22/11/2011

Recruitment status
No longer recruiting

Registration date
12/01/2012

Overall study status
Completed

Last Edited
20/03/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with type 2 diabetes mellitus may eventually develop kidney damage called diabetic nephropathy. Patients with this disease are usually treated with diabetic medication as well as drugs to lower their blood pressure and reduce the deterioration of their kidney function. Despite these treatments, many patients eventually progress to severe kidney disease and require dialysis or kidney transplant. Therefore, there is an unmet medical need for safe and convenient treatments to slow down or reverse the progression of diabetic nephropathy. The aim of this study is to test the safety and effectiveness of a new drug, CCX140-B, in patients with diabetic nephropathy.

Who can participate?
Males and female patients, aged 18-75, who have been diagnosed with diabetic nephropathy.

What does the study involve?
Patients will be randomly allocated to take either capsules of CCX140-B, capsules without a drug (placebo), or a mixture of both capsules. The capsules are to be taken by mouth once daily for a period of 84 days.

What are the possible benefits and risks of participating?
Previous studies have shown evidence that CCX140-B may have an effect on blood glucose and may cause an improvement in protein excretion in the urine, which is an indicator of diabetic nephropathy. CCX140-B appeared to be well tolerated in previous studies, but all new drugs have the potential for unanticipated serious or life-threatening adverse events.

Where is the study run from?
The countries participating in this study are Belgium, Czech Republic, Germany, Hungary, Poland, and the UK.

When is the study starting and how long is it expected to run for?
From November 2011 to August 2012.

Who is funding the study?
ChemoCentryx, Inc. (USA).

Who is the main contact?
Daniel Johnson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01447147

Secondary identifying numbers
CL005_140

Study information

Scientific Title
A randomized, double-blind, placebo-controlled, phase 2 study to evaluate the safety and efficacy of CCX140-B in diabetic nephropathy

Study objectives
The rationale for this phase 2 study is to determine whether CCX140-B is safe and well tolerated and shows evidence of renal or diabetic efficacy after oral administration of CCX140-B once daily for 84 consecutive days to subjects with diabetic nephropathy.

Because CCX140-B blocks the monocyte/macrophage migration from blood to tissues that occurs only during inflammation, it is anticipated that administration of CCX140-B will provide selective therapeutic benefit without compromising general immune surveillance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital Gent Commission on Medical Ethics, Gent, Belgium, 28/09/2011, ref: 2011 /502. All other centres will seek ethics approval before recruitment of the first participant.

Study design
Randomized double-blind placebo-controlled multi-center phase 2 study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetic nephropathy

Interventions
Group A: Four placebo capsules once daily for 84 days. Following the 84-day dosing period, there will be a 28-day safety follow-up period.

Group B: Two 2.5 mg CCX140-B capsules and two placebo capsules once daily for 84 days. Following the 84-day dosing period, there will be a 28-day safety follow-up period.

Group C: Four 2.5 mg CCX140-B capsules once daily for 84 days

Following the 84-day dosing period, there will be a 28-day safety follow-up period.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
CCX140-B

Primary outcome measure

To evaluate the safety and tolerability of CCX140-B in subjects with diabetic nephropathy

Secondary outcome measures
Change from baseline in first morning urinary albumin:creatine ration (ACR)

Overall study start date
30/11/2011

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Aged 18-75 years inclusive, with documented previously diagnosed type 2 diabetes mellitus (as per American Diabetes Association [ADA] criteria)
2. Residual albuminuria despite stable treatment with an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) for at least 8 weeks prior to screening (Albumin:creatinine ratio [ACR] of 200 to 3000 mg/g creatinine, inclusive)
3. Estimated glomerular filtration rate (eGFR) based on serum creatinine determined by Modification of Diet in Renal Disease [MDRD] equation of greater than or equal to 25 mL/min/1. 73 m(2)
4. Must be on a stable dose of an ACE inhibitor or ARB for at least 8 weeks prior to screening, but subjects must not be on both an ACE inhibitor and an ARB
5. Hemoglobin A1c (HbA1c) > 6.0% but not > 10.0% and fasting plasma glucose less than 270 mg /dL at screening

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Approximately 135

Key exclusion criteria
1. Type 1 diabetes mellitus or history of diabetic ketoacidosis
2. Previous renal transplant or known non-diabetic renal disease, except related to hypertension
3. Undergone renal dialysis at any time in the past
4. Received chronic (more than 7 days continuously) systemic glucocorticoid or other

immunosuppressive treatment within 8 weeks of screening
5. Use of bardoxolone, atrasentan or other endothelin antagonist within 8 weeks of screening
6. Received chronic (more than 7 days continuously) non-steroidal anti-inflammatory drug (NSAID) treatment within 2 weeks of screening
7. Cardiac failure (class III or IV), history of unstable angina, symptomatic coronary artery disease, myocardial infarction or stroke within 12 weeks of screening
8. Poorly-controlled blood pressure (systolic blood pressure >155 or diastolic blood pressure >95, with blood pressure measured in the seated position after at least 5 minutes of rest)

Date of first enrolment
30/11/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Belgium

Czech Republic

Germany

Hungary

Poland

United Kingdom

United States of America

Study participating centre
850 Maude Avenue
Mountain View, CA
United States of America
94043

Sponsor information

Organisation
ChemoCentryx, Inc. (USA)

Sponsor details
850 Maude Avenue
Mountain View, CA

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	01/09/2015		Yes	No