

Study to evaluate the effect of CCX140-B on albuminuria in subjects with type 2 diabetes mellitus

Submission date 27/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/12/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/01/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims:

People with type 2 diabetes mellitus may develop kidney failure after a period of time. Albuminuria is the presence of a type of protein (called albumin) in the urine, and may also be a sign of kidney failure. Although the cause of this type of kidney injury is not fully known, the immune system appears to contribute. CCX140-B is a new drug which may prevent certain immune system cells from damaging the kidneys.

This study will test whether albumin levels can be reduced in people with type 2 diabetes mellitus. In this study CCX140-B is an additional therapy; it does not replace the standard treatment for kidney failure or type 2 diabetes mellitus.

Who can participate?

Men and women ages 18 to 75 years with diagnosed type 2 diabetes mellitus, with evidence of some kidney injury.

What does the study involve?

Half of the participants will receive 4 capsules of CCX140-B every day for 12 weeks, and the other half will receive 4 capsules without any drug every day for 12 weeks.

What are the possible benefits and risks of participating?

CCX140-B may be able to prevent kidney damage in future patients who have type 2 diabetes mellitus. Side effects of CCX140-B were mild in nature, however all investigational new drugs have the potential for unanticipated serious or life-threatening side effects.

Where is the study run from?

Centre for Human Drug Research, the Netherlands

When is the study starting and how long is it expected to run for?

Enrolment began in September 2011 and the study finished in June 2012.

Who is funding the study?
ChemoCentryx, USA

Who is the main contact?
Dan Johnson
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01440257

Protocol serial number
CL007_140

Study information

Scientific Title
A randomized, double-blind, placebo-controlled phase 2 study to evaluate the effect of CCX140-B on albuminuria in subjects with type 2 diabetes mellitus

Study objectives
The rationale for this study is to investigate whether CCX140-B treatment of subjects with type 2 diabetes mellitus (T2DM) and albuminuria can reduce albuminuria. 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)

Leiden University Medical Center Medical Ethics Committee, Leiden, Netherlands approved on 29 August 2011, ref: CHDR 1112

Primary study design

Interventional

Study design

Randomized double-blind placebo-controlled single-center phase 2a study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 Diabetes Mellitus with albuminuria

Interventions

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

Control: Four Placebo capsules once daily for 84 days

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

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

1. Change from baseline in 24-hour urinary albumin excretion over 84 days
2. Subject incidence of adverse events over 84 days

Key secondary outcome(s)

Change in baseline of hemoglobin A1c over 84 days

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. Male or female, aged 18-75 years inclusive, with documented previously diagnosed type 2 diabetes mellitus (per American Diabetes Association [ADA] criteria)
2. Albumin:creatinine ratio (ACR) of 200 to 3000 mg/g creatinine, inclusive, based on two values obtained from two first morning urine samples taken on two separate days during the screening period
3. Estimated glomerular filtration rate based on serum creatinine (eGFR), determined by Modification of Diet in Renal Disease [MDRD] equation of greater than or equal to 25 mL/min/1.73 m²
4. Must be on a stable dose of an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) for at least 8 weeks prior to screening
5. Fasting plasma glucose less than 270 mg/dL at screening

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

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. Has 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 (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

01/09/2011

Date of final enrolment

30/06/2012

Locations**Countries of recruitment**

Netherlands

Study participating centre

Centre for Human Drug Research

Leiden

Netherlands

2333 CL

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	01/09/2015	18/01/2019	Yes	No