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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

Registration date
02/12/2011

Overall study status
Completed

Last Edited
18/01/2019

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:
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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01440257

Secondary identifying numbers
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

Study design
Randomized double-blind placebo-controlled single-center phase 2a 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
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 measure
1. Change from baseline in 24-hour urinary albumin excretion over 84 days
2. Subject incidence of adverse events over 84 days

Secondary outcome measures
Change in baseline of hemoglobin A1c over 84 days

Overall study start date
01/09/2011

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Approximately 20

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)

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	18/01/2019	Yes	No