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Progranulin induces autophagy disorder in type 2 diabetic nephropathy

Submission date
15/01/2017

Recruitment status
No longer recruiting

Registration date
03/02/2017

Overall study status
Completed

Last Edited
02/02/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Diabetic kidney disease (nephropathy) develops in nearly 40% of patients with type 2 diabetes (T2DM). Progranulin (PGRN) is a protein which has recently been found to play a role in regulating the breakdown of sugar in the body and the sensitivity of cells to insulin. However there is little known about the role PGRN plays in the development of diabetic nephropathy in people with T2DM. The aim of this study is to investigate the clinical significance and role of PGRN in people with T2DM.

Who can participate?
Adults with T2DM and adults who have normal blood sugar control.

What does the study involve?
All participants attend a single study visit where they have samples of blood taken in order to measure PGRN, blood sugar and insulin levels. Of these participants those who have kidney disease also have small samples taken from their kidneys (biopsy) to look at chemicals indicating cell breakdown.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. There is a small risk of complications such as infection for patients having samples of their kidneys taken.

Where is the study run from?
The First Affiliated Hospital of Xi'an Jiaotong University School of Medicine (China)

When is the study starting and how long is it expected to run for?
March 2013 to August 2016

Who is funding the study?
1. National Natural Science Foundation of China (China)
2. The New Century Excellent Talentsin University from the Ministry of Education (China)

Who is the main contact?
Professor Honzhi Sun
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014074

Study information

Scientific Title
PGRN Links Autophagy: Etiology study of Type 2 diabetic nephropathy

Study objectives
The aim of this study is to investigate the clinical significance and correlations of progranulin (PGRN) and autophagic imbalance in patients with type 2 diabetic nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xi'an Jiao Tong University Ethics Committee, 01/03/2014, ref: 2014074

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
A total of 134 patients with type 2 diabetes and 20 participants with normal glucose tolerance are enrolled. Patients with type 2 diabetes are divided into three groups based on their urinary albumin excretion rate (UAER): simple diabetes mellitus (SDM), early diabetic nephropathy (EDN), and clinical diabetic nephropathy (CDN).

All participants one study visit and provide blood samples when they visit to measure serum PGRN, plasma glucose, plasma insulin and HbA1c. Serum concentrations of PGRN are measured using ELISA.

Renal tissue is obtained from six living allograft donors and 12 diabetic nephropathy patients (taken from the existing participant groups). Autophagy indicators Atg7, LC3, and p62 of renal tissue are detected by Real-time PCR and western blotting.

Intervention Type
Other

Primary outcome measure
1. PGRN serum concentration is measured using ELISAs at baseline and 2 hours after overnight fasting
2. Plasma glucose is measured using glucose oxidase method at baseline and 2 hours after overnight fasting
3. Serum insulin is measured using radioimmunoassay at baseline and 2 hours after overnight fasting
4. HbA1c values are measured using high-performance liquid chromatography at baseline and 2 hours after overnight fasting

Secondary outcome measures

Autophagy indicators Atg7, LC3, and p62 of renal tissue are measured using immunohistochemical examination, real-time PCR and western blotting at baseline, 0, 10, 20 and 40 minutes after overnight fasting.

Overall study start date
03/03/2013

Completion date
01/08/2016

Eligibility

Key inclusion criteria
Patients:
1. Aged between 20 and 80 years old
2. Diagnosed with type 2 diabetes mellitus

Controls:
1. Aged between 32 and 72 years
2. Normal glucose control

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
154

Key exclusion criteria
1. Past history of malignancy
2. Degenerative disease of the nervous system
3. Diabetic macrovascular complications
4. Other endocrine diseases which affect glucose metabolism and lipid metabolism
5. Chronic hepatitis
6. Primary kidney disease
7. Recent inflammatory disease
8. Acute trauma
9. Taking thiazolidinedione drugs in the previous 3 weeks
10. Pregnancy
11. History of drug abuse.

Date of first enrolment
01/08/2014

Date of final enrolment

01/08/2015

Locations

Countries of recruitment
Afghanistan

China

Study participating centre
The First Affiliated Hospital of Xi'an Jiaotong University School of Medicine
Key Laboratory of Environment and Genes Related to Diseases
Ministry of Education
Medical School of Xi'an Jiaotong University
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Sponsor information

Organisation
National Natural Science Foundation of China

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Sponsor type
Government

Organisation
The New Century Excellent Talentsin University from the Ministry of Education

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Government

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Sponsor details

Sponsor type
Government

Website
http://www.nsfc.gov.cn/publish/portal1/

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Funder Name
The New Century Excellent Talentsin University from the Ministry of Education

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/08/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lin Xu (irenewayne@126.com)

IPD sharing plan summary

Available on request