

# This study aims to analyze whether cyclic glycine proline is involved in the self-healing process during the early stages of metabolic dysfunction in people with type 2 diabetes

<b>Submission date</b> 30/07/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

To certain extent, our body has the ability to self-heal. For example, our body produces cyclic glycine proline to keep us healthy and to help recovery from diseases, like diabetes. Diabetes is a metabolic disorder, which can progress to organ dysfunction, including high blood pressure, chronic kidney disease and diabetic peripheral neuropathy. Our hypothesis is that as self-healing mechanism our body produces more cyclic glycine proline during the early stage of diabetes, before developing diabetic complications. If such a healing mechanism is confirmed, it may help us to identify a therapeutic target for improving metabolism and preventing diabetic complications.

### Who can participate?

Male and females aged between 45 and 80 years with medical histories of T2DM without or with hypertension and foot peripheral neuropathy can volunteer to participate in the trial.

### What does the study involve?

Participants will visit hospital once. During the visit, foot sensation is to be assessed using Semmes-Weinstein monofilament, vibration and warm/cold perception threshold tests. These tests are the routine practice for assessing foot sensory function. Fasting blood samples (10ml) and spot urine (30ml) will be collected, and blood pressure is measured during hospital visit.

### What are the possible benefits and risks of participating?

Our body naturally produces cGP keeping the function of IGF-1 normal. When our own cGP production is insufficient we can experience metabolic dysfunction. We will analyze cGP concentration in your plasma samples and to see whether your own cGP production is sufficient to prevent metabolic disorder and whether you need additional cGP to help recovery from T2DM and its complications. There is no risk of participating in the study.

Where is the study run from?

This study will be conducted at the Department of Endocrinology, Tianyou Hospital, Wuhan University of Science and Technology, China.

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

May 2020 to May 2023

Who is funding the study?

The study is co-funded by The Health Commission, Hubei, China, and The cGP Lab Ltd., New Zealand.

Who is the main contact?

Dr J Guan, Jian.guan@thecgplab.com

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

MR-42-23-028752

## Study information

### Scientific Title

Evaluation of the cause-effect relationship of plasma cyclic glycine proline and the manifestations of type 2 diabetes mellitus (T2DM) and its associated vascular complications

### **Study objectives**

There is a cause and effect relationship between circulating Insulin-like growth factor - 1 (IGF-1) function and manifestations of T2DM. IGF-1 function in circulation will be evaluated by measuring plasma concentrations of IGF-1, IGFBP-3 and cyclic glycine-proline (cGP).

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 01/05/2020, The Ethics Committee of Tianyou Hospital, Affiliated to Wuhan University of Science & Technology (9 Tujialing, Wuchang, Wuhan, 430064, China; +86 13554623321; yangyang1003@wust.edu.cn), ref: Approval number: 2021-02-28; Revised approval number LL2024-02-08-01

### **Study design**

Cross-sectional cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cross sectional study

### **Study setting(s)**

Hospital

### **Study type(s)**

Other, Screening

### **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**

During a single hospital visit, fasting blood samples and spot urine samples are taken for biological analysis. Glucose metabolism is evaluated by measuring fasting glucose concentration, HBA1c (%), triglyceride/glucose index. Blood pressure is evaluated by measuring systolic and diastolic blood pressure. Foot diabetic peripheral neuropathy is evaluated by measuring foot sensation using Semmes-Weinstein monofilament test, vibration and warm/cold perceptions tests. Kidney function is evaluated by measuring urine concentration of albumin, albumin /creatinine ratio, plasma urea nitrogen and its ratio with plasma creatinine. In addition plasma lipid profiles and uric acid concentration are also measured.

### **Intervention Type**

Other

### **Primary outcome measure**

During a single hospital visit, the fasting blood samples and spot urine samples are taken for biological analysis. As a primary outcome, glucose metabolism is evaluated by measuring fasting glucose concentration, HBA1c (%), triglyceride/glucose index.

### **Secondary outcome measures**

Measured at a single time point:

1. Blood pressure is evaluated by measuring systolic and diastolic blood pressure
2. Foot diabetic peripheral neuropathy is evaluated by measuring foot sensation using Semmes-Weinstein monofilament test, vibration and warm/cold perceptions tests
3. Kidney function is evaluated by measuring urine concentration of albumin, albumin/creatinine ratio, plasma urea nitrogen and its ratio with plasma creatinine

### **Overall study start date**

01/05/2020

### **Completion date**

01/05/2023

## **Eligibility**

### **Key inclusion criteria**

1. Male and female participants, 45 to 80 years of age
2. Medical history and clinical diagnosis of T2DM either without or with medical history and clinical diagnosis of dyslipidaemia, hypertension and/or clinical diagnosis of foot DPN

### **Participant type(s)**

Healthy volunteer, Patient

### **Age group**

Adult

### **Lower age limit**

45 Years

### **Upper age limit**

80 Years

### **Sex**

Both

### **Target number of participants**

80

### **Total final enrolment**

77

### **Key exclusion criteria**

1. Type 1 diabetes
2. Pregnancy related T2DM and/or hypertension
3. Poorly controlled glucose metabolism (fasting glucose >15 mmol/L)
4. T2DM with severe complications such as diabetes ketoacidosis, stage 4 diabetic nephropathy and diabetic foot ulcer
5. Other causes of hypertension and chronic kidney diseases
6. Drug, injury or neurological condition induced peripheral neuropathy
7. Medical history of degenerative conditions
8. Cognitive impairment and major mental health issues
9. Severe depression and anxiety

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

01/05/2023

## Locations

**Countries of recruitment**

China

**Study participating centre**

The Department of Endocrinology, Tianyou Hospital, Affiliated to Wuhan University of Science & Technology

9 Tujialing, Wuchang

Wuhan

China

430064

## Sponsor information

**Organisation**

The cGP LAB, New Zealand

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**Sponsor type**

Industry

**Website**

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**Organisation**

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**Sponsor type**

University/education

**Funder(s)****Funder type**

Government

**Funder Name**

The Health Commission, Hubei, China

**Funder Name**

The cGP Lab Ltd. Auckland, New Zealand

**Results and Publications****Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/05/2025

**Individual participant data (IPD) sharing plan**

The datasets (raw data) generated during and/or analyzed during the current study will be available upon request from Dr Jian Guan (jian.guan@thecgplab.com)

Raw data without private information can be shared after the publication of the main data. The consent from participants has been obtained and there is no ethical and legal restriction. Some information collected and recorded is in Chinese.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		21/01/2025	06/06/2025	Yes	No