ISRCTN76855091 https://doi.org/10.1186/ISRCTN76855091

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

Submission date
30/07/2024

Recruitment status
No longer recruiting

Registration date
31/07/2024

Overall study status
Completed

Last Edited
06/06/2025

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
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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other, Screening

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
80 years

Sex
All

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

Organisation
Tianyou Hospital, Wuhan University of Sciences and Technology

Funder(s)

Funder type
Government

Funder Name
The Health Commission, Hubei, China

Funder Name
The cGP Lab Ltd. Auckland, New Zealand

Results and Publications

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?
Results article		21/01/2025	06/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes