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Investigating the levels of extrachromosomal circular DNA in serum of newly diagnosed type 2 diabetes mellitus patients

Submission date
07/12/2020

Recruitment status
No longer recruiting

Registration date
21/12/2020

Overall study status
Completed

Last Edited
21/01/2025

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
Extrachromosomal circular DNA (eccDNA) has long been known to form from proto-oncogenes which are normal genes present in the human genome which, when altered by mutation, can become a gene that can contribute to cancer (an oncogene). The formation of eccDNA has also been linked to aging.

The levels of eccDNA circulating in the body outside of cells in type 2 diabetes patients have not previously been investigated. The aim of this study is to assess the levels of serum of eccDNA in newly diagnosed type 2 diabetes patients.

Who can participate?
Newly diagnosed type 2 diabetes patients and healthy volunteers.

What does the study involve?
Participants will provide blood samples which will be tested to find eccDNA that are present at high or low levels in newly diagnosed type 2 diabetes.

What are the possible benefits and risks of participating?
There is no direct benefit to the participant by taking part in this study. Data collected may be used to support future clinical studies in this population.

There are no risks of participating in this study. Participants will receive treatment for their illness that follows the National Chinese guidelines for treating this type of illness.

Where is the study run from?
The First Affiliated Hospital of Wannan Medical College, Yijishan Hospital (China)

When is the study starting and how long is it expected to run for?
From May 2020 to May 2021

Who is funding the study?
The National Natural Science Foundation of China (China) and "Peak" Training Program for Scientific Research of Yijishan Hospital, Wannan Medical College (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pilot study to assess abnormal expression of serum extrachromosomal circular DNA between newly diagnosed type 2 diabetes mellitus patients and healthy participants.

Study objectives
To determine the abnormal expression of cell-free circulating extrachromosomal circular DNA in newly diagnosed type 2 diabetes mellitus patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2020, Scientific Research and New Technology Ethics Committee of Wannan Medical College Yijishan Hospital (2 Zheshanxi Rd, Wuhu, 241001, China; +86 (0)5535939912; lvkun315@126.com), ref: 2020022

Study design
Observational study of cases and controls

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Peripheral blood samples will be collected from newly diagnosed type 2 diabetes mellitus patients and healthy participants. Serum DNA extractions were performed using QIAamp Circulating Nucleic Acid Kit (Qiagen). For elimination of linear DNA and enrichment of eccDNA, 25 ng of plasma/serum DNA will be treated with 5 units of Plasmid-Safe ATP-dependent DNase (Epicentre) in a 50 µl reaction system at 37°C for 5 min, followed by column purification using MinElute Reaction Cleanup Kit (Qiagen). EccDNA enriched from 25 ng of plasma/serum DNA will be processed using Nextera XT DNA Library Preparation Kit (Illumina). DNA libraries will be sequenced on Illumina NovaSeq 6000 with 150 bp paired end mode according to the manufacturer's instructions. Real-time PCR will be used to verify the differentially expressed eccDNA candidates. The correlation between the differentially expressed eccDNA and other clinical factors will also be evaluated.

Intervention Type
Other

Primary outcome(s)
1. Serum eccDNA levels in peripheral blood samples of newly diagnosed type 2 diabetes mellitus patients measured using high throughput sequencing at the time of data collection

Key secondary outcome(s))
1. Clinical factors associated with the differentially expressed eccDNA measured using patient records at the time of data collection

Completion date
01/07/2021

Eligibility

Key inclusion criteria

1. Type 2 diabetes mellitus diagnosed according to the 1999 World Health Organization diagnostic criteria

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
146

Key exclusion criteria
1. No clinical evidence of severe kidney or liver diseases, chronic viral or bacterial infection, inflammatory diseases, tumors, or diabetic ketoacidosis

Date of first enrolment
21/07/2020

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Wannan Medical College
Yijishan Hospital
2 Zheshanxi Rd
Wuhu
China
241001

Sponsor information

Organisation
Wannan Medical College

ROR
https://ror.org/037ejjy86

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
'Peak' Training Program for Scientific Research of Yijishan Hospital, Wannan Medical College

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/01/2024	21/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes