

Development of a non-invasive and accurate diagnostic method for type 2 diabetes using acetone in urine samples

Submission date 23/11/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/11/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Type 2 diabetes (T2D) is a common condition that causes the level of sugar (glucose) in the blood to become too high and accounts for more than 90% of the confirmed cases of diabetes. It has become a common underlying metabolic disease and is expected to affect 380 million people worldwide in 2025. At present, the diagnosis of type 2 diabetes is mainly based on fasting plasma glucose (FPG), the oral glucose tolerance test (OGTT), and glycosylated hemoglobin (HbA1c), but there are a few methods of non-invasive screening. The aim of this study is to study the association between acetone levels in the urine headspace (the gas above the contents of a sealed urine sample) and T2D .

Who can participate?

Patients with type 2 diabetes and healthy people with a normal physical examination, aged 18-90 years

What does the study involve?

Participants are asked to provide 2 ml urine samples and levels of acetone are measured using proton transfer reaction mass spectrometry.

What are the possible benefits and risks of participating?

Participation in this study will give the participants a better understanding of their physical health and diabetic diseases. Only waste urine routine samples are used, without risk.

Where is the study run from?

The Chinese Academy of Sciences and the Second Affiliated Hospital of Anhui Medical University (China)

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

March 2020 to May 2022

Who is funding the study?

1. The Second Affiliated Hospital of Anhui Medical University (China)
2. Hefei Institutes of Physical Science, Chinese Academy of Sciences (China)

Who is the main contact?

Xue Zou

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

LHJJ2020006

Study information

Scientific Title

Non-invasive and accurate diagnosis of type 2 diabetes using urinary acetone: a prospective multicenter study

Study objectives

Urinary acetone can be used for the diagnosis of type 2 diabetes (T2D).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/03/2020, The Second Hospital of Anhui Medical University Ethics Committee (No. 678, Furong Road, Hefei Economic and Technological Development Zone, Anhui Province, China; +86 (0)551 63806061; aydefyllwyhbgs@126.com), ref: YX2021-113

Study design

Observational case-control study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Each participant is asked to provide a 2 ml urine sample. Acetone in the headspace of urine in sealed bottles is quantitatively analyzed by mass spectrometry.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Urinary acetone is measured using proton transfer reaction mass spectrometry in less than 8 h after sampling

Key secondary outcome(s)

1. Fasting blood glucose is detected using a blood glucose monitor in less than 4 h after sampling
2. A1c is detected using a glycosylated hemoglobin automatic analyzer in less than 4 h after sampling

Completion date

01/05/2022

Eligibility**Key inclusion criteria**

1. All T2D patients diagnosed in each hospital and found to have abnormal high fasting plasma glucose (FPG) levels less than 1 week before the experiments
2. Healthy subjects chosen from people undergoing health examinations in these hospitals
3. Age range: 18-90 years

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Key exclusion criteria

Participants in the healthy control group are required to have no neurological, endocrine or other systemic diseases and no acute and chronic inflammatory or infectious diseases

Date of first enrolment

20/04/2021

Date of final enrolment

01/04/2022

Locations**Countries of recruitment**

China

Study participating centre

The Second Hospital of Anhui Medical University

No. 678, Furong Road

Economic and Technological Development Zone

Hefei

China

230601

Study participating centre

The Anhui Provincial Hospital/The First Affiliated Hospital of USTC

No. 17, Lujiang Road

Luyang District

Hefei

China

230002

Study participating centre

The First Affiliated Hospital of Anhui Medical University
120 Wanshui Road
Shushan District
Hefei
China
230022

Sponsor information

Organisation

Hefei Institutes of Physical Science

ROR

<https://ror.org/046n57345>

Organisation

Second Hospital of Anhui Medical University

ROR

<https://ror.org/047aw1y82>

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China (22076190, 21876176, 21705152, 21777163, 62171433)

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 Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Youth Innovation Promotion Association, CAS (2019432)

Alternative Name(s)

YIPA

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

China

Funder Name

Chinese Academy of Sciences, Functional Development Program of Instruments and Equipment (Y9BS0C1291)

Funder Name

Joint Fund of the Second Affiliated Hospital of Anhui Medical University and the Center of Medical Physics and Technology of Hefei Institute of Physical Sciences of Chinese Academy of Sciences (LHJJ2020006)

Funder Name

Anhui Provincial Institute of Translational Medicine (2017zhyx12)

Funder Name

Anhui Medical University Research Fund (2021xkj166)

Alternative Name(s)

, , AHMU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Chinese Academy of Sciences (xzou@cmpt.ac.cn). All raw data detected by mass spectrometry and clinical data that do not affect the privacy of participants can be obtained within 1 year after the relevant papers are published. All units and individuals interested in the experiment can obtain the experimental data for analyses without commercial interest by email consultation. The consent of the participant will be obtained and the participant's name and other private details will not be provided.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			24/11/2021	No	No