

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

<b>Submission date</b> 23/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/11/2021	<b>Condition category</b> 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  
xzou@cmpt.ac.cn

## Contact information

### Type(s)

Scientific

### Contact name

Mr Xue Zou

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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; aydefyllwyhbg@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?
<a href="#">Protocol file</a>			24/11/2021	No	No