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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

Registration date
25/11/2021

Overall study status
Completed

Last Edited
26/11/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
10/03/2020

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

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
400

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

Sponsor details
350 Shushanhu Road
Hefei
China
230031
+86 (0)551 65591245
chyshen@aiofm.ac.cn

Sponsor type
Research organisation

Website
http://www.hf.cas.cn/

ROR
https://ror.org/046n57345

Organisation
Second Hospital of Anhui Medical University

Sponsor details
678 Furong Road
Economic and Technological Development Zone
Hefei
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+86 (0)551 63869420
512130761@qq.com

Sponsor type
Hospital/treatment centre

Website
http://www.ay2fy.com/

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 Wěiyuánhuì, 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
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

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?
Protocol file			24/11/2021	No	No