

Increased brain iron deposition in type 2 diabetes

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
04/11/2023	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
07/11/2023	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
30/01/2026	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Diabetes is believed to be connected to an issue with how your body manages iron, and how it stores excess iron. The part of the brain called the basal ganglia, which has a lot of iron, goes through changes in how it stores iron in people with type 2 diabetes. These changes can affect both motor skills and thinking abilities, but we're not completely sure how it all works yet.

We want to find out more about how the brain handles iron in the basal ganglia in people with type 2 diabetes who also have diabetic peripheral neuropathy (DPN). To do this, we'll use a technique called quantitative susceptibility mapping (QSM). We're also going to see if these changes in iron in the brain are connected to how well people with type 2 diabetes can move and think.

Who can participate?

Type 2 diabetes patients and healthy controls aged 40 - 70 years

What does the study involve?

Cognitive and motor assessments, blood biochemical tests, and brain QSM imaging.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Shandong Provincial Hospital Affiliated to Shandong First Medical University (China)

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

January 2021 to December 2022

Who is funding the study?

Shandong Provincial Hospital Affiliated to Shandong First Medical University (China)

Who is the main contact?

Lingfei Guo, glfsci@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

DC23-2069

Study information

Scientific Title

Increased brain iron deposition in the basial ganglia is associated with cognitive and motor dysfunction in type 2 diabetes

Acronym

T2DM

Study objectives

Brain iron deposition increased in type 2 diabetes.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 18/11/2019, Ethical Committee of the Institutional Review Board (IRB) of Shandong Institute of Medical Imaging (324 Jing-wu Road, Jinan, 250021, China; +86 531-68776789; kewaichu@126.com), ref: 2019-002

Study design

Single-centre observational cross-sectional cohort study

Primary study design

Observational

Study type(s)

Diagnostic, Prevention

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

To explore the changing mode of brain iron metabolism in the basal ganglia in type 2 diabetes patients with diabetic peripheral neuropathy (DPN) using quantitative susceptibility mapping (QSM) and further to investigate whether these changes are associated with cognitive and motor function in type 2 diabetes patients.

All subjects undergo cognitive and motor assessments, blood biochemical tests, and brain QSM imaging.

Intervention Type

Behavioural

Primary outcome(s)

Measured at baseline and 3 months:

1. Cognitive ability is measured using the Beijing version of the Montreal Cognitive Assessment (MoCA)
2. The presence and severity of diabetic peripheral sensorimotor polyneuropathy is measured using The Toronto Clinical Scoring System (TCSS)
3. Depression and anxiety is measured using Hospital Anxiety and Depression Scale (HADS)
4. Movements, the individual's risk of falls and other adverse consequences is measured using the Timed Up and Go (TUG) test and Gait speed

Key secondary outcome(s)

Measured by self report or by blood test at baseline and 3 months:

1. Age (years)
2. Gender
3. Height (m), weight (kg), body mass index (kg/m²)
4. HbA1c
5. Hypertension
6. Diabetes
7. Hyperlipidemia
8. Total cholesterol (mmol/l)
9. Triglyceride (mmol/l)
10. High density lipoprotein (mmol/l)
11. Low density lipoprotein (mmol/l)
12. Smoking and drinking
13. Education (year)
14. Total-tau (mmol/l)

15. A β 1-42 (mmol/l)

16. P-Tau-181

17. APOE

Completion date

30/12/2022

Eligibility

Key inclusion criteria

The inclusion criteria for all subjects are:

1. Age from 40 to 70 years old
2. Right-handedness

Healthy controls:

1. No history of diabetes and glycated hemoglobin (HbA1c) level between 4 and 6%
2. No history of severe mental or neurologic diseases
3. No history of head trauma, surgery, or tumors
4. No alcohol or drug abuse.

Patients:

1. All patients met the diagnostic criteria of type 2 diabetes of the 2023 American Diabetes Association, and the diagnosis of diabetic peripheral neuropathy conformed to the Toronto consensus criteria.
2. Diabetic peripheral neuropathy patients had at least one type of neuropathy characterized by numbness, prickling, and burning pain primarily in the extremities, and the signs included weakening or disappearance of ankle reflexes or symmetric decrease of distal sensory symmetry.

Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

40 years

Upper age limit

70 years

Sex

All

Total final enrolment

535

Key exclusion criteria

The exclusion criteria for all patients are:

1. History of brain trauma, surgery, or tumors
2. Acute complications of type 2 diabetes
3. Severe hypertension
4. History of severe cerebrovascular, neurological, or mental diseases
5. Alcohol or drug abuse
6. MRI contraindications

Date of first enrolment

01/02/2021

Date of final enrolment

30/11/2022

Locations

Countries of recruitment

China

Study participating centre

Shandong Provincial Hospital Affiliated to Shandong First Medical University

324 Jing-wu Road

Jinan

China

250021

Sponsor information

Organisation

Shandong Provincial Hospital Affiliated to Shandong First Medical University

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Shandong Provincial Hospital Affiliated to Shandong First Medical University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Lingfei Guo, glfsci@163.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		25/03/2025	30/01/2026	Yes	No