ISRCTN20008650 https://doi.org/10.1186/ISRCTN20008650

Increased brain iron deposition in type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
04/11/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/11/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/11/2023	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
Prof Lingfei Guo

ORCID ID
http://orcid.org/0000-0002-4885-625X

Contact details
Shandong Provincial Hospital Affiliated to Shandong First Medical University
Jinan
China
250021
+86 531-68776789
guolingfei@sdfmu.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Prevention

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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 cholesterin (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. Aβ1-42 (mmol/l)
16. P-Tau-181
17. APOE

Overall study start date
01/01/2021

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

Age group
Adult

Lower age limit

40 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
800

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

Sponsor details
324 Jing-wu Road, Jinan, Shandong
Jinan
China
250021
+86 531-68776789
guolingfei@sdfmu.edu.cn

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shandong Provincial Hospital Affiliated to Shandong First Medical University

Results and Publications

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

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysedduring the current study will be available upon request from Lingfei Guo, glfsci@163.com

IPD sharing plan summary
Available on request