Neuroimaging research of brain aging in the elderly in the community

Submission date	Recruitment status	Prospectively registered
20/02/2024	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/02/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
28/02/2024	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Background and study aims

This project seeks to investigate how the aging process affects the brain and its impact on cognitive abilities and physical movement in adults who are middle-aged and elderly. Additionally, it aims to understand the mechanisms that connect changes in the aging brain to alterations in mental health and cognitive function. By doing so, it aims to enhance our ability to diagnose and predict conditions related to brain aging and to pinpoint potential treatments.

Who can participate? All subjects aged 40 - 70 years

What does the study involve?

The research includes evaluating how people think and move, testing blood for various substances, and taking images of the brain using a technique called quantitative susceptibility mapping (QSM).

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? November 2018 to December 2028

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

Dr Lingfei Guo

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Neuroimaging study on the correlation between brain aging and cognitive-motor function in the middle-aged and elderly population

Study objectives

This project aims to explore the correlation between brain aging and cognitive-motor function in the middle-aged and elderly population and to elucidate pathways from age-related brain changes to neuropsychiatric changes, improving diagnosis and prognosis and identifying therapeutic targets.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 18/11/2019, Shandong Institute of Medical Imaging (324 Jing-wu Road, Jinan, Shandong, Jinan, 250021, China; +86 68776789; kewaichu@126.com), ref: 2019-002

Study design

Observational cross sectional

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community, Hospital

Study type(s)

Diagnostic, Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Brain aging

Interventions

We intend to utilize the most current Quantitative susceptibility mapping (QSM) data available to examine and evaluate the correlation between iron accumulation and neuropsychiatric disorders. Extensive health data will be utilized to evaluate and compare vascular, inflammatory, metabolic, and genetic risk factors for brain ageing in the elderly and progression through techniques such as regression analyses, and mediation modelling.

Intervention Type

Other

Primary outcome measure

Brain iron is measured using Quantitative susceptibility mapping (QSM) at baseline, 2 years and 5 years.

Secondary outcome measures

Brain iron measured using QSM at 2 years.

Overall study start date

01/11/2018

Completion date

01/12/2028

Eligibility

Key inclusion criteria

- 1. Age from 40 to 80 years old
- 2. Right-handedness

Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

40 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

3000

Key exclusion criteria

- 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

01/12/2018

Date of final enrolment

01/11/2028

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 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

01/01/2029

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