

Study of brain health in women of childbearing age

Submission date 29/03/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/04/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this project is to investigate the changes in brain cognitive ability and body movement as well as to systematically assess the structural and functional characteristics of the brain in women of childbearing age. By utilizing structural MRI, functional MRI and advanced quantitative imaging techniques (e.g., QSM, DTI, etc.), the brain imaging characteristics of women of childbearing age are depicted. With the help of multimodal data and machine learning methods, an individualized brain health risk assessment model is constructed to provide a basis for early identification of brain function abnormalities. The ultimate goal is to provide scientific and individualized brain health management strategies for women of childbearing age, and to promote the development of the concept of integrating reproductive health and brain health.

Who can participate?

Women of childbearing age between 18 and 49 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 structural MRI, functional MRI and advanced quantitative imaging techniques (e.g., QSM, DTI, etc.).

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. However, it can provide scientific and individualized brain health management strategies for women of childbearing age and promote the development of the concept of integrating reproductive health and brain health.

Where is the study run from?

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (China)

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

January 2019 to December 2029

Who is funding the study?

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (China)

Who is the main contact?
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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 of changes in brain cognitive-motor function in women of childbearing age

Study objectives

This study aims to investigate the trajectory of cognitive function and motor ability in women of reproductive age, and to systematically elucidate how the structural and functional changes in the brain during pregnancy affect the neuropsychiatric state, and to reveal the underlying biological mechanisms. Through this study, we hope to optimize the diagnostic process, improve the accuracy of prognostic assessment, and pinpoint potential therapeutic targets to improve the health of women of childbearing age.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 18/06/2019, The Medical Ethics Committee of Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (2 Jian-guo Xiao Jing-san Road, Jinan, 250001, China; +86 531 8902 9000; 18254887757@126.com), ref: 20190618

Study design

Observational cross sectional

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community, Hospital

Study type(s)

Diagnostic, Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Changes in cognitive and motor function in women of childbearing age

Interventions

After enrollment, participants will undergo assessments of thinking and movement abilities, blood tests for various substances, and brain imaging using quantitative susceptibility mapping (QSM) technology. The total duration of observation is 10 years, from November 1, 2019, to December 1, 2029. Follow-up will start from enrollment, with QSM brain iron measurements taken at baseline, 2 years, and 5 years, with overall follow-up continuing until December 1, 2029.

Intervention Type

Other

Primary outcome measure

Brain iron is measured using Quantitative susceptibility mapping (QSM) at pre-pregnancy, pregnancy and post-partum.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/11/2019

Completion date

01/12/2029

Eligibility**Key inclusion criteria**

1. Women of childbearing age between 18 and 49 years
2. Right-handedness

Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

49 Years

Sex

Female

Target number of participants

1000

Key exclusion criteria

1. History of brain trauma, surgery, or tumors
2. History of severe cerebrovascular, neurological, or mental diseases
3. Alcohol or drug abuse
4. MRI contraindications

Date of first enrolment

01/12/2019

Date of final enrolment

01/11/2026

Locations**Countries of recruitment**

China

Study participating centre

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University

2 Jian-guo Xiao Jing-san Road

Jinan

China

250001

Sponsor information**Organisation**

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Government

Funder Name

Jinan Maternity And Child Care 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

31/12/2029

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Linfeng Yang, ylf19860928@126.com

IPD sharing plan summary

Available on request