ISRCTN44876504 https://doi.org/10.1186/ISRCTN44876504

Study of brain health in women of childbearing age

Submission date	Recruitment status	[ ] Prospectively registered
29/03/2025	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/04/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/04/2025	Other	[ ] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic, Quality of life

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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
Female

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
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Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Jinan Maternity And Child Care 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 Linfeng Yang, ylf19860928@126.com

IPD sharing plan summary
Available on request