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Investigate the correlation between multimodal neuroimaging and urinary dysfunction and brain functional abnormalities

Submission date	Recruitment status	[_] Prospectively registered
24/03/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/03/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the central nervous mechanism of the occurrence and development of urinary dysfunction. By using multimodal neuroimaging techniques, the researchers hope to explore the correlation between urinary dysfunction and abnormal brain function, which could aid in better clinical decision-making and treatment.

Who can participate?
Patients with various diseases related to lower urinary tract symptoms who were admitted to the outpatient and inpatient departments of the urology department of Wuxi No.2 People's Hospital (Jiangnan University Medical Center) could participate in this study.

What does the study involve?
Participants will undergo multimodal MRI scans and an anxiety scale assessment. The study will use a variety of advanced techniques to examine these samples. As part of the study, participants will undergo a free medical exam.

What are the possible benefits and risks of participating?
Participants will benefit from free medical tests, which can provide valuable health information. There are no risks involved in participating in this study.

Where is the study run from?
Wuxi No.2 People's Hospital (Jiangnan University Medical Center), China

When is the study starting and how long is it expected to run for?
April 2024 to June 2027

Who is funding the study?
The National Natural Science Foundation of China, China

Who is the main contact?
Professor Ninghan Feng, n.feng@njmu.edu.cn

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ChiCTR2400092006

Study information

Scientific Title
Research on the mechanism and clinical application of multimodal neuroimaging to evaluate the correlation between urinary dysfunction and abnormal brain function

Study objectives
To explore the central nervous mechanism of the occurrence and development of urinary dysfunction.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/04/2024, Medical Ethics Committee of the Wuxi No.2 People’s Hospital, Jiangnan University Medical Center (No.68 Zhongshan Road, Liangxi District, Wuxi City, Jiangsu Province, 214000, China; +86 15152220089; 9862022074@jiangnan.edu.cn), ref: 2024 Y-26

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Screening

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied
Patients with urinary dysfunction

Interventions
Serum samples were collected from patients with various lower urinary tract symptoms (such as frequent urination, urgency, dysuria and incomplete voiding, etc.), related diseases (including prostatitis, cystitis, overactive bladder, neurogenic bladder, etc.) and healthy control subjects in the clinical setting. Neuro-psychological tests and multimodal neuroimaging were completed, and the differences in morphometry were compared to explore the central nervous system mechanisms underlying the occurrence and development of urinary dysfunction diseases.

Intervention Type
Other

Primary outcome measure
The central nervous system mechanisms underlying the occurrence and development of urinary dysfunction diseases were measured using multimodal neuroimaging scans performed the afternoon after admission.

Secondary outcome measures
1. Anxiety measured using the Hamilton Anxiety Rating Scale (HAM-A) later in the morning of the second day after admission

Overall study start date
22/04/2024

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Diagnostic criteria for interstitial cystitis: (satisfy both of the following conditions)
1.1. Pain in the bladder area or frequent urination and urgency
1.2. Intravesical instillation of normal saline to expand the bladder (pressure reaches 80cmH2O and maintained for 3 minutes), observing more than three quadrants with 10 or more bleeding points as positive.
2: Diagnostic criteria for prostatitis:
2.1. Those who meet the diagnostic criteria for chronic prostatitis according to Western medicine
2.2. Disease duration exceeds 3 months
2.3. No oral treatment with other medications within 2 weeks before entering the study cycle
3. Diagnostic criteria for bladder cancer:
3.1. Pathological diagnosis is the gold standard
4. Diagnostic criteria for prostate cancer:
4.1. Pathological diagnosis is the gold standard
5. Diagnostic criteria for overactive bladder (OAB):
1. Urgency score in the OABSS questionnaire is 2 points or above, and the total score is 3 points or above, excluding other pathological causes.

Control Group Enrollment Criteria:
Healthy examination personnel with age, gender, and education level matched to the refractory lower urinary tract dysfunction patients were selected from our hospital's health examination center using frequency matching. Among them, those with a HAMA scale score > 7 were included in the anxiety control group.

Participant type(s)
Healthy volunteer, Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Patients with urethral stenosis, urinary tract stones, urinary tract infection, urinary tract tumors, or neurogenic bladder
2. Women who are breastfeeding or pregnant
3. Patients with severe heart, liver, kidney, brain, and hematopoietic system diseases
4. Patients with central nervous system infection, head injury, epilepsy, multiple sclerosis, toxic metabolic diseases, Parkinson's disease, or intracranial tumors
5. Patients who have undergone pelvic surgery for pelvic organ prolapse or urinary incontinence
6. Patients with a family history of genetic diseases, a history of schizophrenia or personality changes, or a history of alcohol/drug dependence
7. Patients who have taken related cognitive-improving drugs
8. Patients with severe heart, liver, kidney, brain, and hematopoietic system diseases, or gynecological diseases such as vaginitis
9. Patients with contraindications to MRI scanning (such as implanted electronic or metal devices)

Date of first enrolment
13/11/2024

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
China

Study participating centre
Wuxi No.2 People’s Hospital (Jiangnan University Medical Center)
No.68 Zhongshan Road, Liangxi District
Wuxi City, Jiangsu Province
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214000

Sponsor information

Organisation
Wuxi No.2 People's Hospital

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+86 13861892528
9862022074@jiangnan.edu.cn

Sponsor type
Hospital/treatment centre

Website
http://www.wx2h.com/

ROR
https://ror.org/0399zkh42

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

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

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Ninghan Feng, n.feng@njmu.edu.cn.

The data information may include the demographic data of participants and the main indicators of the experiment. This part has been indicated in the informed consent form, and the data will be collected and used after the consent of the participants. The relevant ethics have been reviewed and approved by the Ethics Committee.

IPD sharing plan summary
Available on request