ISRCTN98143643 https://doi.org/10.1186/ISRCTN98143643

How does electroacupuncture improve symptoms of postpartum depression by regulating glutamate metabolism: a clinical and mechanistic study

Submission date
11/04/2025

Recruitment status
Recruiting

Registration date
14/04/2025

Overall study status
Ongoing

Last Edited
23/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Postpartum depression (PPD) is a serious condition that affects new mothers, causing persistent low mood, anxiety, irritability, fatigue, and other symptoms. It can be more severe and long-lasting than typical postpartum emotional changes. This study aims to understand the differences in certain biological markers between PPD patients, individuals with major depressive disorder (MDD), and healthy postpartum women. It also looks at how these markers change before and after treatment in PPD patients and compares PPD patients to MDD patients after treatment.

Who can participate?
Women aged 18 - 49 years who have been diagnosed with postpartum depression or major depressive disorder according to the DSM-5, or who are healthy postpartum women.

What does the study involve?
Participants will receive electroacupuncture treatment at specific points on the body twice a week for four weeks, totaling eight sessions. This involves using a mild electrical current at acupuncture points. They will also receive usual care, which includes health education, social support, lifestyle adjustments, and psychotherapy sessions twice a week for four weeks.

What are the possible benefits and risks of participating?
The potential benefits include improvement in depressive symptoms. Possible risks include adverse reactions such as bleeding and pain from the acupuncture.

Where is the study run from?
The study is conducted at Shanghai University of Traditional Chinese Medicine, Shenzhen Hospital, and Maternal and Child Health Hospital of Luohu District, Shenzhen City (China)

When is the study starting and how long is it expected to run for?
January 2025 to January 2029

Who is funding the study?
The study is funded by the National Natural Science Foundation of China (Grant No. 8247153215).

Who is the main contact?
Prof. Hong Zhao, hongzhao2005@aliyun.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Hong Zhao

ORCID ID
https://orcid.org/0000-0001-8211-9483

Contact details
Shanghai University of Traditional Chinese Medicine, Shenzhen Hospital, No.16 Xiantong Road, Liantang Street, Luohu District
Shenzhen
China
518002
+86 (0)755 25160866
hongzhao2005@aliyun.com

Additional identifiers

Study information

Scientific Title
Clinical efficacy and glutamate metabolism mechanism of electroacupuncture for postpartum depression patient

Study objectives
Study One: Investigating the similarities and differences in glutamate metabolism among women with Postpartum Depression (PPD), Major Depressive Disorder (MDD), and healthy postpartum women.
Study Two: Verifying that electroacupuncture treats PPD by specific regulatory effects on glutamate metabolism.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 20/01/2025, Ethics Committee of Shenzhen Luohu District Hospital of Traditional Chinese Medicine (Shanghai University of Traditional Chinese Medicine, Shenzhen Hospital, No. 16 Xiantong Road, Liantang Street, Luohu District, Shenzhen 518002, China, Shenzhen, 518002, China; +86 (0)755 82311699; lhzyykjk@163.com), ref: 2025-LHQZYYYXLL-KY-005

Primary study design
Interventional

Study design
Cross-sectional observational study followed by prospective randomized controlled trial with concurrent controls

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postpartum depression patients, major depressive disorder patients, and healthy postpartum women.

Interventions
This study will be conducted across two centers to investigate the differences in glutamate metabolism among women with postpartum depression (PPD), major depressive disorder (MDD), and healthy postpartum women through analysis of tongue coating, fecal, and blood samples.

This study will be conducted prospectively across two centers. Participants will be randomly assigned to three groups: experimental group (electroacupuncture + usual care for PPD patients), control group 1 (usual care for PPD patients), and control group 2 (electroacupuncture + usual care for MDD patients). Randomization will be concealed using a random number table prior to group allocation. Only after enrollment will the researchers and participants be informed of the group assignments. Due to the nature of the interventions, blinding of researchers and participants during the intervention process is not feasible. However, data analysts will be blinded during data analysis.

Experimental Group: Electroacupuncture + usual care for postpartum depression (PPD) patients.
Control Group 1: Usual care for PPD patients.
Control Group 2: Electroacupuncture + usual care for patients with major depressive disorder (MDD).
*Electroacupuncture: Acupuncture points selected include Baihui (GV20), Yintang (EX-HN3), Zhongwan (CV12), Qihai (CV6), Guanyuan (CV4), and Zusanli (ST36) bilaterally.
Electroacupuncture is applied to Baihui and Yintang points using a sparse-dense wave with a frequency of 2 Hz/100 Hz. The intensity is adjusted to a level that the patient can tolerate. Each session lasts for 30 minutes, twice a week, for a total of 4 weeks, resulting in 8 treatment sessions.
*Usual care: Includes health education, social support, lifestyle adjustment, and psychotherapy. The intervention lasts for 4 weeks in total. Psychotherapy sessions are 45 to 60 minutes long, conducted twice a week.

Intervention Type
Mixed

Primary outcome(s)
Response rate after treatment. Definition of efficacy (Response): A reduction rate of ≥ 50% in the score of the 17-item Hamilton Depression Rating Scale (HAMD-17) before and after treatment is defined as effective (Response).
Calculation formula for reduction rate:
(Pre-treatment HAMD-17 score – Post-treatment HAMD-17 score)/Pre-treatment HAMD-17 score × 100%.

Key secondary outcome(s)
Current secondary outcome measures as of 23/04/2025:
The following secondary outcome measures are assessed at pre-treatment and post-treatment:
1. Depression severity is measured using the Hamilton Depression Rating Scale, 17-item (HAMD-17)
2. Anxiety severity is measured using the Hamilton Anxiety Scale (HAMA)
3. Sleep patterns of women during the postpartum period measured using the Postpartum Sleep Quality Scale (PSQS) and the Pittsburgh Sleep Quality Index (PSQI) scale
4. Glutamate metabolism levels are measured in tongue coating and feces using 16S rRNA gene sequencing and metaproteomic analysis, in serum using enzyme-linked immunosorbent assay (ELISA), in plasma using ELISA, high-performance liquid chromatography, and targeted mass spectrometry, and in PBMCs using quantitative polymerase chain reaction

Previous secondary outcome measures:
1. Depression severity is measured using the Hamilton Depression Rating Scale, 17-item (HAMD-17) at pre-treatment and post-treatment
2. Self-rated depression severity is measured using the Self-Rating Depression Scale (SDS) at pre-treatment and post-treatment
3. Anxiety severity is measured using the Hamilton Anxiety Scale (HAMA) at pre-treatment and post-treatment
4. Self-rated sleep quality is measured using the Self-Rating Scale of Sleep (SRSS) at pre-treatment and post-treatment
5. Glutamate metabolism levels are measured using tongue coating, feces, serum, plasma, and PBMC at pre-treatment and post-treatment

Completion date
28/01/2029

Eligibility

Key inclusion criteria
1. They meet the diagnostic criteria for postpartum depression or major depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), or they are healthy postpartum women.
2. They are females aged between 18 and 49 years.
3. They have signed the informed consent form and voluntarily agree to participate in this study.

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. Pregnant women.
2. Alcohol dependence or dependence on addictive drugs.
3. Suicidal tendencies, with suicidal behavior within the past year.
4. Received antidepressant medication treatment within one month prior to the trial.
5. History of or current bipolar disorder, schizophrenia, organic brain disease, intellectual disability, or antisocial personality disorder.
6. Contraindications to electroacupuncture, such as severe heart disease (e.g., having a pacemaker), severe coagulation dysfunction, or skin damage and ulcers at the acupuncture sites.

Date of first enrolment
24/04/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
China

Study participating centre
Shanghai University of Traditional Chinese Medicine, Shenzhen Hospital
Shanghai University of Traditional Chinese Medicine, Shenzhen Hospital, No.16 Xiantong Road, Liantang Street, Luohu District
Shenzhen
China
518002

Study participating centre
Maternal and Child Health Hospital of Luohu District, Shenzhen City
No. 2013 Taibai Road, Luohu District

Shenzhen
China
518019

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

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

Individual participant data (IPD) sharing plan
Thedatadets generated during and/or analysed during the current study will be avaible upon request from Prof. Hong Zhao, hongzhao2005@aliyun.com

IPD sharing plan summary
Available on request