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Can electroacupuncture improve symptoms of mild to moderate postnatal depression?

Submission date
28/04/2019

Recruitment status
No longer recruiting

Registration date
23/05/2019

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Mental and Behavioural Disorders

[ ] 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 (postnatal) depression can start in parents before or after the birth of a baby. It is a serious problem because it can affect bonding between the parents and baby and childcare routines. If a mother is breastfeeding, it might not be safe to take antidepressant tablets, because breast milk can contain some of the drug. There is a new drug called Zulresso that is taken through a vein using a drip. It is safe to use during breastfeeding but is expensive. Electroacupuncture involves very fine needles being inserted into the skin at certain points and electric current being passed through them. Electroacupuncture is cheap and does not affect breastfeeding. This study aims to investigate whether electroacupuncture can help with postpartum depression symptoms.

Who can participate?
Women who have postpartum depression within one year of their baby's birth.

What does the study involve?
Participants will be randomly allocated to one of two groups. They will not know which group they are in. Both groups will receive supportive psychotherapy. One group will receive electroacupuncture twice a week for 6 weeks. The other group will have sham electroacupuncture, where the needles are not put in the correct places and the current is not turned on.

What are the possible benefits and risks of participating?
Both groups will receive treatment in the form of supportive psychotherapy. There are some potential side effects of electroacupuncture, including bleeding, bruising and pain, but these are generally mild and will stop quickly.

Where is the study run from?
China Academy of Chinese Medical Sciences (China)

When is the study starting and how long is it expected to run for?
January 2018 to December 2022.

Who is funding the study?
The Ministry of Science and Technology of the People's Republic of China

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
None

Study information

Scientific Title
The effect of electroacupuncture on mild to moderate postpartum depression: a randomized controlled single-blind study.

Study objectives
The morbidity of mild to moderate postpartum depression is increasingly rising. However, the need of lactation prevents the use of regular oral antidepressants. The new antidepressant Zulresso (brexanolone), which has been approved by the FDA for postpartum depression, costs USD 34,000 dollars per treatment course per person. Acupuncture might offer an advantage in mild to moderate postpartum depression because it does not affect breastfeeding. However,

the supporting evidence is weak. This trial is designed to provide high-level evidence regarding whether electroacupuncture is effective in relieving the symptoms of mild to moderate postpartum. We hypothesize that the effect of electroacupuncture on mild to moderate postpartum depression will be better than that of sham electroacupuncture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/07/2018, Acupuncture and Moxibustion Hospital, China Academy of Chinese Medical Science (No.16, Nanxiaojie, Dongzhimennei, Beijing; +86 010-64060868; yuxc@acutimes.com), ref: 2018-05-25-3-2
2. Approved 10/09/2018, Beijing Obstetrics and Gynecology Hospital, Capital Medical University (17 Qihelou St, Dongcheng District, Beijing; +86 010-85968407; fcyylunli@163.com), ref: 2018-KY-053-01

Study design
Two-armed single-blind randomized controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Postpartum depression

Interventions
Eligible patients will be randomly assigned into treatment group or control group using SAS software. Group assignment information will be kept in sealed envelopes. According to their group assignment, patients will receive either electroacupuncture plus supportive psychotherapy or sham electroacupuncture plus supportive psychotherapy. Both groups will receive treatment twice a week for 6 weeks, and the whole treatment course is 12 sessions.
The treatment group will receive the electroacupuncture and the selected acupoints are as follows: Ophryon (EX-HN 3), Xinshu (BL 15), Geshu (BL 17), Ganshu (BL 18), Shenshu (BL 23), Hegu (LI 4), Sanyinjiao (Sp 6), Zhongwan (CV 12) and Baihui (GV 20).
The control group will receive sham electroacupuncture. The practitioner will needle locations beside the acupoints at superficial layers and use the electroacupuncture device without current output as the sham acupuncture.

Intervention Type

Other

Primary outcome measure
Severity of depression using the first 17 answers on Hamilton Depression Rating Scale (HAM-D). The 17-HAMD will be measured by a professional psychiatrist at baseline and weeks 2, 4 and 6

Secondary outcome measures
1. Severity of depression using the Montgomery–Åsberg Depression Rating Scale (MADRS) at baseline and weeks 2, 4 and 6
2. Postpartum depression assessed using the Edinburgh Postnatal Depression Scale at baseline, weeks 2, 4 and 6 and week 10 (4 weeks after treatment end)
3. Alertness assessed using the Stanford Sleepiness Scale at baseline and weeks 2, 4 and 6
4. Maternal functional status assessed using the Barkin Index of Maternal Functioning at baseline, weeks 2, 4 and 6 and week 10 (4 weeks after treatment end)
5. Severity of depression using the first 17 answers on Hamilton Depression Rating Scale (HAM-D) at week 10 (4 weeks after treatment end)
6. Participant assessment of depression assessed using the Patient Health Questionnaire(PHQ-9) at baseline and weeks 2, 4 and 6

Overall study start date
20/01/2018

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Diagnosed with postpartum depression according to The Diagnostic and Statistical Manual of Mental Disorders (DSM) by psychiatrists
2. Conceived naturally or artificially
3. Aged 20–50 years
4. Overall score of ≥9 on the Edinburgh Postnatal Depression Scale (EPDS)
5. Diagnosed with mild to moderate postpartum depression according to the 17-item Hamilton Depression Scale (17-HAMD)
6. Postpartum depression onset time within 1 year after delivery
7. Can accept electroacupuncture treatment and complete the prescribed course of treatment
8. Agrees to participate in the study willingly and voluntarily and signs the informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants

60

Total final enrolment
60

Key exclusion criteria
1. Brain disease or mental retardation, or have difficulty understanding the contents of questionnaires or are unable to communicate effectively
2. History of epilepsy, bipolar disorder, schizophrenia or schizoaffective disorder
3. History of suicide attempts
4. Diagnosed with non-depressive psychosis by psychiatrists
5. Addicted to alcohol or drugs
6. Received antidepressant therapy within the past month
7. Hemorrhagic diseases or infectious diseases or otherwise unable to receive acupuncture therapy

Date of first enrolment
01/10/2018

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
China

Study participating centre
Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences
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Study participating centre
Beijing Obstetrics and Gynecology Hospital
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Study participating centre

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Sponsor type
Government

ROR
https://ror.org/042pgcv68

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology of the People's Republic of China

Alternative Name(s)
Chinese Ministry of Science and Technology, Ministry of Science & Technology, People Republic of China, , Ministry of Science and Technology (China), State Science and Technology Commission, MOST

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
China

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 07/06/2021:
We tend to publish the protocol before December 2021. We plan to publish results in February 2022.

Previous publication and dissemination plan:
We tend to publish the protocol before February 2020. We plan to publish results in December 2020.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other