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The use of acupuncture for the treatment of depression

Submission date	Recruitment status
10/12/2007	No longer recruiting
Registration date	**Overall study status**
04/03/2008	Completed
Last Edited	**Condition category**
16/05/2012	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A single-blind, randomised, sham controlled study of electroacupuncture in accelerating the onset of antidepressant action of selective serotonin reuptake inhibitors via serotonergic mechanisms

Study objectives
Depression is a worldwide mental health problem, with a lifetime prevalence of about 20%. The currently available antidepressant treatments, represented by selective serotonin reuptake inhibitors (SSRIs), are incomplete and unsatisfactory. The most apparent is the delay in the onset of action of SSRIs, which has hampered the use of this class of drugs.

Hypothesis:
Electroacupuncture acceleration of the response to SSRIs is achieved through its potentiation of serotonin (5-HT) release by inhibiting autoreceptor (5-HT1A/1B) activities, uptake, and turnover.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethical Committee of the First Teaching Hospital, Hebei Medical University on the 19th June 2006 (ref: 66).

Study design
A single-centre, single-blind, randomised, sham controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
This is a six-week, single-blind, randomised, sham controlled study. A total of 66 untreated patients with MDD will be recruited. Under single-blind condition, patients will be randomly assigned to paroxetine (PRX) combined with active or sham electroacupuncture (EA) for six weeks. PRX dose is initiated at 10 mg/day and escalated to maximum 40 mg/day within one week. EA intervention is conducted by electrically stimulating two acupoints: Yin-Tang (EX-HN3) and Bai-Hui (DU-20) for 45 minutes daily.

Both groups of the patients will receive orally administered PRX for six weeks. The dose is initiated at 10 mg/day and escalated to maximum 40 mg/day within one week. The choice of PRX, but not other SSRIs, is because the slow onset of PRX action has been well demonstrated in our preliminary and previous studies. Treatments with the dose range defined have been reported to yield optimal clinical outcomes in Chinese depressed patients. Concomitant use of other psychoactive medications is not allowed. If significantly clinical conditions have to require such medications, patients will be asked to withdraw from the study. Patients who have poor compliance with medication schedules (below 80%) will also be removed from the study.

Meanwhile, active or sham EA intervention is conducted daily for six weeks. For active EA, a pair of stainless steel needles of 0.25 mm diameter are inserted at a depth of 10 - 20 mm obliquely into Bai-Hui (Du-20) and Yin-Tang (EX-HN3), through which electric stimulation with continuous waves with 2 Hz at 6 voltages are delivered. The intensities of stimulation are adjusted to a level at which patients feel most comfortable. To ensure the active procedure as identical as the sham procedure, the inserted needles are affixed with adhesive tapes. For the sham treatment, the needles are inserted into two non-traditionally defined points at 1 - 1.5 cm around the acupoints used for active EA, but immediately taken out and put back into plastic needle guiding tubes. The needles contained in the tubes are then affixed on the point skins with adhesive tapes and stimulated electrically as described above. Our initial practice and other studies have demonstrated that this novel sham acupuncture procedure enables well-controlled blinding for patients.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Paroxetine

Primary outcome measure
1. Efficacy, measured using the HAMD-17, CGI-S, and Sheehan disability scale (SDS)
2. Adverse events, assessed using the treatment emergent symptom scale (TESS)

Assessments will be conducted at baseline and at day 3, 7, 10, 14, 21, 28, 35, and 42.

Secondary outcome measures
1. Clinical response, defined as less than 50% reduction from baseline on HAMD-17
2. Remission, defined as a score 7 points or less on the HAMD-17

Assessments will be conducted at baseline and at day 3, 7, 10, 14, 21, 28, 35, and 42.

Overall study start date
01/09/2006

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Either gender aged 25 - 65 years
2. Have first-episode major depressive disorder (MDD) diagnosed from the diagnostic and statistical manual of mental disorders, 4th edition (DSM-IV)
3. Scores on the 17-item Hamilton depression rating scale (HAMD) and clinical global impression of severity (CGI-S) are at least 20 and 4 points, respectively
4. Have not yet received any psychoactive medications

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Unstable medical conditions
2. Have suicidal attempts or aggressive behaviour
3. Previously experienced manic, hypomanic, or mixed episode
4. Immediate family members were or are diagnosed for bipolar or psychotic disorders
5. Treatment with investigational drugs in past six months
6. Alcoholism or drug abuse in past one year
7. Have needle phobia

Date of first enrolment
01/09/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
China

Hong Kong

Study participating centre
School of Chinese Medicine
Pokfulam
Hong Kong
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Sponsor information

Organisation
The Health and Health Services Research Fund (HHSRF), Food and Health Bureau of Hong Kong

Sponsor details
18/F, Murray Building, Garden Road, Central, Hong Kong
Hong Kong
China
050031

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The First Teaching Hospital (China) - Intramural Research Fund

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No