

The use of acupuncture for the treatment of depression

Submission date 10/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2012	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Zhang-Jin Zhang

Contact details
School of Chinese Medicine
The University of Hong Kong
10 Sassoon Road
Pokfulam
Hong Kong
-

Additional identifiers

Protocol serial number
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-HT_{1A/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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

-

Sponsor information**Organisation**

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

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

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