

# Effect of acupuncture on fMRI and Iowa Gambling Task (IGT) in postherpetic neuralgia (PHN) patients

<b>Submission date</b> 08/10/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/07/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Post-herpetic neuralgia (PHN) is a condition in which a feeling of pain arises as a consequence of the herpes zoster (HZ) virus infection and it damages the corresponding neurological system. Unfortunately, existing treatments often do not work against PHN. Traditional Chinese acupuncture offers some advantages: it is simple to perform, has little systemic effect and few side effects. There is no published evidence on the effects of acupuncture on the central nervous system and this study is about the therapeutic effects of acupuncture on PHN patients.

### Who can participate?

Patients admitted to the Department of Acupuncture, Massage and Traumatology of Shanghai Sixth People's Hospital (China) and diagnosed with post-herpetic neuralgia diagnoses.

### What does the study involve?

Participants are randomly allocated to one of two groups: Group A (acupuncture group) receives acupuncture (Ashi point) for 3 weeks; Group B (sham acupuncture group, also called the control group) receives acupuncture (non-Ashi point) for 3 weeks. Patients and investigators do not know which treatment they receive (this is called blinding). Follow up continues for 14 days after treatment.

Oxycodone 5-30mg/day or more orally to be used as 'rescue medication' (to relieve symptoms immediately) for pain control.

### What are the possible benefits and risks of participating?

There are no known risks to participants. All participants, including controls, will receive all the tests which may improve their treatment of PHN.

### Where is the study run from?

The study takes place at Department of Acupuncture Massage and Traumatology at the Shanghai Sixth People's Hospital (China).

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

The study will start recruiting participants between December 2011 and July 2012. Follow-up examinations will continue until October 2012.

Who is funding the study?

Chinese Traditional Medical and Drug Administration Bureau (China)

Who is the main contact?

Dr Mi Yiqun

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Mi Yiqun

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

A clinical study of the effect of acupuncture on fMRI and IGT in postherpetic neuralgia patients: a prospective, double-blind, randomised controlled trial

### Study objectives

1. That functional magnetic resonance imaging (fMRI) signal and Iowa Gambling Task (IGT) were different among postherpetic neuralgia (PHN) patients and control patients.

2. The acupuncture can affect the signal of fMRI, the outcome of the IGT, quality of life and reduce the dosage required of oral pain-related drugs in PHN patients

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Shanghai Sixth Peoples Hospital, Shanghai JiaoTong University, 16 March 2011, ref: 2011-19

### **Study design**

Prospective, double blind, randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Postherpetic neuralgia

### **Interventions**

PHN patients were randomized to receive acupuncture (Ashi point), or sham acupuncture for 3 weeks

Rescue medication - Oxycodone 5-30mg/day orally (or more) was used as rescue medication for pain controlled at more than 3 on the VAS and the frequency of acute pain flare-ups more than 3 times per day.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Oxycodone

### **Primary outcome measure**

1. fMRI signal change, IGT results at baseline and 14 days after treatment
2. Visual Analogue Scale (VAS), measured at baseline and 1, 2, 3, 7 and 14 days after treatment
3. Pain flare-ups per day during days 3, 7, 14 after treatment

### **Secondary outcome measures**

1. SF-36 at baseline, 14 days after treatment
2. Dosage of rescue drug (Oxycodone) consumed per day at 3, 7, and 14 days after treatment
3. Presence, frequency and duration of adverse effects at 7 and 14 days after treatment

### **Overall study start date**

01/12/2011

### **Completion date**

01/10/2012

## **Eligibility**

### **Key inclusion criteria**

1. Age greater than 60 years
2. Weighs over 40kg
3. History of pain is longer than 3 months
4. Pain on Visual Analogue Scale (VAS) >3 (0-10 VAS scale), with acute pain flares that occurred more than 3 times per day
5. Refractory to formal treatment such as antiepileptic medicine, antidepressants, opioids, physical treatments and epidural block
6. No history of severe liver and renal diseases
7. PHN patients whose pain area was at T1-12 level
8. Male and female participants

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

38 patients

### **Key exclusion criteria**

1. Withdraws from the study
2. Poor effect, intolerant to the study
3. Uncooperative and unable to finish the self evaluation (VAS, QOL and SF-36)
4. Coagulation disturbances
5. Allergies to drug
6. Malignancy

**Date of first enrolment**

01/12/2011

**Date of final enrolment**

30/07/2012

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

Department of Acupuncture, Massage and Traumatology

Shanghai

China

200233

## **Sponsor information**

**Organisation**

Shanghai Sixth People's Hospital (China)

**Sponsor details**

600 Yi-Shan Road

Shanghai

China

200233

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.6thhosp.com/eng/>

**ROR**

<https://ror.org/049zrh188>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Chinese Traditional Medical and Drug Administration Bureau ref: 2009ZL23

## **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