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

Submission date
08/10/2011

Recruitment status
No longer recruiting

Registration date
27/10/2011

Overall study status
Completed

Last Edited
14/07/2015

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
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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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 patents whose pain area was at T1-12 level
8. Male and female participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Government

Funder Name
Chinese Traditional Medical and Drug Administration Bureau ref: 2009ZL23

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes