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# The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients

**Submission date**
02/10/2011

**Recruitment status**
No longer recruiting

**Registration date**
28/10/2011

**Overall study status**
Completed

**Last Edited**
06/12/2012

**Condition category**
Nervous System Diseases

[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:
Postherpetic neuralgia (PHN) is a nerve pain that occurs at the site of a previous attack of a condition called shingles. Neuralgia is a term that describes nerve pain. Postherpetic neuralgia is nerve pain which continues 3-6 months after the shingles rash has healed. PHN can have a severe impact on a patients quality of life. The health care costs related to persistent PHN puts a heavy economic burden and stress on families and societies. Unfortunately, PHN is often does not respond very well to the existing treatments.
The aim of this study is observe the effect of pregabalin in PHN patents. Treatment of PHN with pregabalin is safe and effective in relieving pain and sleep interference. However, to date no known studies investigating the effect of pregabalin on the central nerve system measured using functional Magnetic Resonance Imaging.

Who can participate?
Patients diagnosed with postherpetic neuralgia, aged over 60 years and weighing over 40kg.

What does the study involve?
Participants were randomly allocated to one of two 2 groups:
Pregabalin group), which received pregabalin twice a day for 14 days.
Placebo group, which received a placebo (dummy drug) twice a day for 14 days.
Oxycodone was used as rescue medication for pain if required.

What are the possible benefits and risks of participating?
All participants received treatments which may improve the symptoms of PHN.
There were no known risks associated with participating in this trial.

Where is the study run from?
Pain Management Center, Xinhua Hospital

When is the study starting and how long is it expected to run for?
Participants were enrolled the study between December 2011 and November 2012 and follow-up examinations will continued until December 2012.

Who is funding the study?
Shanghai Education Committee, China ref: 11YZ56

Who is the main contact?
Prof M A Ke,
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# 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**
The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients: a prospective, double blind, randomised controlled trial

**Study objectives**
1. That fMRI signal and IGT were different among postherpetic neuralgia (PHN) patients and control patients.

2. The drug (pregabalin) can affect signal of fMRI, the outcome of IGT, quality of life and reduce the oral pain-related drugs dosage of PHN patients

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Xinhua Hospital affiliated to Shanghai Jiaotong Universty School of Medicine, 17 of March 2011, ref: 2011-003

## 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 pregabalin 150mg twice a day (Bid) or placebo for 2 weeks.

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

## Intervention Type
Drug

## Phase
Not Applicable

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

## Primary outcome measure

1. fMRI signal change, IGT results at baseline, days 14 after treatment
2. Visual Analogue Scale (VAS), measured at baseline, days1, 2, 3,7,14 after treatment
3. Flare pain per day during days 3, 7, 14 after treatment

### Secondary outcome measures
1. SF-36 at baseline, days 14 after treatment
2. Dosage of rescue drug (Oxycodone) consumed per day at days3, 7, and 14 after treatment
3. Presence, frequency and duration of adverse effects at 7, 14 days

### Overall study start date
01/12/2011

### Completion date
30/12/2012

## Eligibility

### Key inclusion criteria
1. Age greater than 60 years and over 40kg of body weight
2. Pain history is longer than 3 months
3. Pain on Visual Analogue Scale (VAS) >3 (0-10 VAS scale), the frequency of acute pain flares occurred more than 3 times per day
4. Refractory to formal treatment such as antiepileptic medicine, antidepressants, opioids and physical treatments and epidural block
5. No history of severe liver and renal diseases

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
40 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, qulaity of life [QOL] and SF-36)
4. Coagulation disturbances
5. Allergies to drug
6. Malignancy

### Date of first enrolment
01/12/2011

### Date of final enrolment

30/12/2012

# Locations

### Countries of recruitment
China

### Study participating centre
**Department of Anesthesiology**
Shanghai
China
200092

# Sponsor information

### Organisation
Xinhua Hospital (China)

### Sponsor details
Department of Anesthesiology
Shanghai Jiaotong University School of Medicine
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/04dzvks42

# Funder(s)

### Funder type
Government

### Funder Name
Shanghai Education Committee (China) ref: 11YZ56

# 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