

# The clinical study of peripheral subcutaneous neuromodulation in postherpetic neuralgia treatment

|  |  |  |
|--|--|--|
| <b>Submission date</b><br>20/10/2007   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/10/2007 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>10/06/2021       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <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 MA Ke

### Contact details

Department of Anaesthesiology and Pain Centre  
Shanghai Sixth Peoples Hospital  
Shanghai JiaoTong University  
600 Yi-Shan Road  
Shanghai  
China  
200233

-  
marke72@163.com

## Additional identifiers

### Protocol serial number

N/A

## Study information

**Scientific Title**

The clinical study of peripheral subcutaneous neuromodulation in postherpetic neuralgia treatment

**Study objectives**

We hypothesise:

1. That peripheral subcutaneous neuromodulation has analgesic efficacy in chronic refractory Postherpetic Neuralgia (PHN) patients
2. This simple neuromodulation can improve the quality of life and reduce the oral drugs dosage of patients

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Ethics Committee of Shanghai Sixth People's Hospital, Shanghai Jiaotong University on the 15th August 2007.

**Study design**

Prospective randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Postherpetic Neuralgia (PHN)

**Interventions**

Arm 1: peripheral subcutaneous neuromodulation

Arm 2: sham peripheral subcutaneous neuromodulation

Arm 3: naive control group

Treatment will continue for three weeks (two time per week), follow-up will continue for 6 months.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Analgesic efficacy (Visual Analogue Scale [VAS]) and Quality Of Life (QOL) from 3 days to 1 month after neuromodulation.

**Key secondary outcome(s))**

1. QOL
2. 36-item Short Form health survey (SF-36)

3. Oral analgesic drugs dose
4. Three skin fiber (C-, A $\alpha$  and A $\beta$ ) functional measurement

All measured from 1 month to 6 months after neuromodulation.

**Completion date**

01/10/2008

## Eligibility

**Key inclusion criteria**

1. Patients were between 60 and 90 years old
2. Patients must have pain present for more than 6 months after the healing of shingles skin rash
3. Patients at screening must have a score of greater than or equal to 40 mm on the pain visual analogue scale

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

102

**Key exclusion criteria**

1. Patients withdrawn from the study
2. Patients can't take self-assessment of the pain due to PHN

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

01/10/2008

## Locations

**Countries of recruitment**

China

**Study participating centre**

**Department of Anaesthesiology and Pain Centre**  
Shanghai  
China  
200233

## Sponsor information

### Organisation

Shanghai Sixth Peoples Hospital (China)

### ROR

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

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Shanghai Sixth People's Hospital (China) - clinical 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/12/2013   | 10/06/2021 | Yes            | No              |