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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 20/10/2007 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/10/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 10/06/2021 | Nervous System Diseases | |

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

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

### Secondary outcome measures
1. QOL
2. 36-item Short Form health survey (SF-36)
3. Oral analgesic drugs dose
4. Three skin fiber (C-, Aâ and Aä) functional measurement

All measured from 1 month to 6 months after neuromodulation.

### Overall study start date
01/09/2007

### 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

### Age group
Senior

### Sex
Both

### Target number of participants
120

### 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)

### Sponsor details
c/o Dr MA Ke
Department of Anaesthesiology and Pain Centre
Shanghai JiaoTong University
600 Yi-Shan Road
Shanghai
China
200233
+86 (0)21 64369181 8648
macoo74@hotmail.com

### Sponsor type
Hospital/treatment centre

### 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

## 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/12/2013 | 10/06/2021 | Yes | No |