

The clinical study of peripheral subcutaneous neuromodulation in postherpetic neuralgia treatment

Submission date 20/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2021	Condition category 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

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Additional identifiers

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.

Primary study design

Interventional

Study design

Prospective randomised controlled trial

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 α and A β) 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?
Results article		01/12/2013	10/06/2021	Yes	No