The clinical study of peripheral subcutaneous neuromodulation in postherpetic neuralgia treatment

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/10/2007		☐ 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

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Contact details

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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 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. OOL
- 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

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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