

The clinical study of intercostal nerve pulsed radiofrequency in postherpetic neuralgia

Submission date 10/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/07/2013	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

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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 intercostal nerve pulsed radiofrequency in postherpetic neuralgia: A randomised controlled trial.

Study objectives

1. That pulsed radiofrequency of intercostals nerve was effective and safe in chronic refractory postherpetic neuralgia (PHN) patients
2. This pulsed radiofrequency can improve the quality of life and reduce the oral pain-related drugs dosage of PHN patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The ethics committee of Xinhua Hospital (affiliated to Shanghai Jiaotong University School of Medicine) approved on the 16th of March 2010 (ref: 2010-002)
2. The ethics committee of Shanghai Sixth People's Hospital approved on the 28th of October 2009 (ref: 2009-96)

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 neuraglia (PHN)

Interventions

Patients were randomised to receive one of the following treatments, once a week for 3 weeks:

1. Pulsed radiofrequency (42 degree, 120 second) of the intercostal nerve (Thoracic 1 to T12 level)
2. Sham procedure, apparatus was left in test mode without the appropriate power output

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Visual Analogue Scale (VAS) score, measured at baseline, days 3, 7, 14, 30 and 60, 6 months and 1 year
2. Flare pain per day during days 3, 7, 14, 30, 60 and at 6 months
3. Neurometer CPT/C (Neurotron, Inc) to measure three fiber function
4. SF-36 at baseline, 2 months, 6 months and 1 year following-up

Secondary outcome measures

1. Need to PRF again or other invasive operation at 2 day, 6 month or 1 year following-up
2. Dosage of rescue drug consumed per week at the end of treatment and after 4 weeks follow-up - including Tramadol and/or acetaminophen - and the dosage of combined drug, anti-depressive drug (amitriptyline)
3. Presence, frequency and duration of adverse effects at 7, 14, 30, and 60 days

Overall study start date

22/02/2008

Completion date

28/05/2011

Eligibility

Key inclusion criteria

1. Age greater than 60 years
2. PHN history is longer than 3 months
3. Pain on Visual Analogue Scale (VAS) >3 (0-10 VAS scale)
4. PHN affected nerve sectors were thoracic nerves from T1 to T12 level
5. Refractory to formal treatment such as antiepileptic medicine, antidepressants, opioids and physical treatments and epidural block

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

96

Key exclusion criteria

1. Exclusion criteria included withdraws from the study
2. Poor effect, intolerant to the study

3. Uncooperative and unable to finish the self evaluation (VAS, QOL and SF-36)
4. Coagulation disturbances
5. Allergies to local anaesthetic
6. Malignancy

Date of first enrolment

22/02/2008

Date of final enrolment

28/05/2011

Locations

Countries of recruitment

China

Study participating centre

Department of Anesthesiology

Shanghai

China

200092

Sponsor information

Organisation

Xinhua Hospital (China)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04dzvks42>

Funder(s)

Funder type

Government

Funder Name

Shanghai Education Funding Committee (China)

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	results	01/01/2013		Yes	No