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The clinical study of intercostal nerve pulsed radiofrequency in postherpetic neuralgia

Submission date	Recruitment status	[ ] Prospectively registered
10/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/07/2013	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 Anesthesiology
Xinhua Hospital
Shanghai Jiaotong University School of Medicine
1665 Kongjiang Road
Shanghai
China
200092
macoo74@hotmail.com

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 Universty 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
Department of Anesthesiology
Shanghai Jiaotong University School of Medicine
1665 Kongjiang Road
Shanghai
China
200092
marke72@163.com

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