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The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients

Submission date
02/10/2011

Recruitment status
No longer recruiting

Registration date
28/10/2011

Overall study status
Completed

Last Edited
06/12/2012

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Postherpetic neuralgia (PHN) is a nerve pain that occurs at the site of a previous attack of a condition called shingles. Neuralgia is a term that describes nerve pain. Postherpetic neuralgia is nerve pain which continues 3-6 months after the shingles rash has healed. PHN can have a severe impact on a patients quality of life. The health care costs related to persistent PHN puts a heavy economic burden and stress on families and societies. Unfortunately, PHN is often does not respond very well to the existing treatments.
The aim of this study is observe the effect of pregabalin in PHN patents. Treatment of PHN with pregabalin is safe and effective in relieving pain and sleep interference. However, to date no known studies investigating the effect of pregabalin on the central nerve system measured using functional Magnetic Resonance Imaging.

Who can participate?
Patients diagnosed with postherpetic neuralgia, aged over 60 years and weighing over 40kg.

What does the study involve?
Participants were randomly allocated to one of two 2 groups:
Pregabalin group), which received pregabalin twice a day for 14 days.
Placebo group, which received a placebo (dummy drug) twice a day for 14 days.
Oxycodone was used as rescue medication for pain if required.

What are the possible benefits and risks of participating?
All participants received treatments which may improve the symptoms of PHN.
There were no known risks associated with participating in this trial.

Where is the study run from?
Pain Management Center, Xinhua Hospital

When is the study starting and how long is it expected to run for?
Participants were enrolled the study between December 2011 and November 2012 and follow-up examinations will continued until December 2012.

Who is funding the study?
Shanghai Education Committee, China ref: 11YZ56

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients: a prospective, double blind, randomised controlled trial

Study objectives
1. That fMRI signal and IGT were different among postherpetic neuralgia (PHN) patients and control patients.
2. The drug (pregabalin) can affect signal of fMRI, the outcome of IGT, quality of life and reduce the oral pain-related drugs dosage of PHN patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xinhua Hospital affiliated to Shanghai Jiaotong Universty School of Medicine, 17 of March 2011, ref: 2011-003

Study design
Prospective double blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postherpetic neuralgia

Interventions
PHN patients were randomized to receive pregabalin 150mg twice a day (Bid) or placebo for 2 weeks.

Rescue medication: Oxycodone 5-30mg/day or more orally was used as rescue medication for pain controlled at VAS more than 3 and the frequency of acute pain flares more than 3 times per day.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pregabalin

Primary outcome(s)
1. fMRI signal change, IGT results at baseline, days 14 after treatment
2. Visual Analogue Scale (VAS), measured at baseline, days1, 2, 3,7,14 after treatment
3. Flare pain per day during days 3, 7, 14 after treatment

Key secondary outcome(s))
1. SF-36 at baseline, days 14 after treatment
2. Dosage of rescue drug (Oxycodone) consumed per day at days3, 7, and 14 after treatment
3. Presence, frequency and duration of adverse effects at 7, 14 days

Completion date
30/12/2012

Eligibility

Key inclusion criteria

1. Age greater than 60 years and over 40kg of body weight
2. Pain history is longer than 3 months
3. Pain on Visual Analogue Scale (VAS) >3 (0-10 VAS scale), the frequency of acute pain flares occurred more than 3 times per day
4. Refractory to formal treatment such as antiepileptic medicine, antidepressants, opioids and physical treatments and epidural block
5. No history of severe liver and renal diseases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Withdraws from the study
2. Poor effect, intolerant to the study
3. Uncooperative and unable to finish the self evaluation (VAS, qulaity of life [QOL] and SF-36)
4. Coagulation disturbances
5. Allergies to drug
6. Malignancy

Date of first enrolment
01/12/2011

Date of final enrolment
30/12/2012

Locations

Countries of recruitment
China

Study participating centre
Department of Anesthesiology
Shanghai
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200092

Sponsor information

Organisation
Xinhua Hospital (China)

ROR
https://ror.org/04dzvks42

Funder(s)

Funder type
Government

Funder Name
Shanghai Education Committee (China) ref: 11YZ56

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration