

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	☒ Prospectively registered ☐ Protocol
Registration date 28/10/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/12/2012	Condition category Nervous System Diseases	☐ 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

Contact name

Prof MA Ke

Contact details

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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 University 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, days 1, 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 days 3, 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, quality 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

China

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