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Clinical study of effects of intramuscular diazepam in chronic postherpetic neuralgia

Submission date
11/01/2018

Recruitment status
No longer recruiting

Registration date
24/01/2018

Overall study status
Completed

Last Edited
30/05/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Postherpetic neuralgia is lasting nerve pain in an area previously affected by shingles. It seriously affects the patient's sleep, mood and quality of life. After treatment there are still some patients who suffer from neuropathic pain and it is still a difficult clinical problem. Diazepam is a long-acting drug used in insomnia and sedation. Animal studies have shown that an injection of diazepam can treat neuropathic pain. The aim of this study is to assess the effects of diazepam on postherpetic neuralgia, anxiety, depression and quality of life, and its safety and side effects.

Who can participate?
Patients aged 18 to 80 with postherpetic neuralgia

What does the study involve?
Participants are randomly allocated to two groups. Those in group 1 are given diazepam injections for 3 days. Those in group 2 are given saline (salt water) injections instead. The pain experienced after treatment is assessed for each patient every day for the next 3 months.

What are the possible benefits and risks of participating?
The participants could have better pain relief. The main possible risks are the side effects of diazepam.

Where is the study run from?
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine) (China)

When is the study starting and how long is it expected to run for?
February 2018 to July 2019

Who is funding the study?
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine) (China)

Who is the main contact?
Prof. Ke Ma

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XINHUA2018-02

Study information

Scientific Title
Clinical trial of effects of intramuscular diazepam in chronic postherpetic neuralgia

Study objectives
1. Intramuscular diazepam is effective and safe when administered for chronic postherpetic neuralgia patients.
2. Treatment of Intramuscular diazepam can improve the quality of life of chronic postherpetic neuralgia patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiaotong University School of Medicine, 26/12/2017, ref: XHEC-C-2017-105

Study design
Single-center double-blinded randomized controlled clinical study

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Neuralgia

Interventions
78 participants are randomly allocated to two groups. Those in group 1 (n=39) are given diazepam 10mg intramuscularly for 3 days. Those in group 2 (n=39) are given saline instead. The basic treatment is oral administration of Gabapentin 0.3g t.i.d. The pain experienced after treatment is assessed for each patient every day for the next 3 months.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Pain, measured using the visual analogue score (VAS) during the treatment and at 7 days, 14 days, 21 days, 28 days, 2 months and 3 months post-treatment.
2. The frequency and intensity of the pain outbreak during the treatment and at 7 days, 14 days, 21 days, 28 days, 2 months and 3 months post-treatment
3. The dosage of Gabapentin per day during the treatment

Secondary outcome measures
1. Intensity of anxiety, measured using the PHQ-9 evaluation scale during the treatment and at 7 days, 14 days, 21 days, 28 days, 2 months and 3 months after treatment
2. Intensity of depression, measured by the GAD-7 anxiety screening scale during the treatment and at 7 days, 14 days, 21 days, 28 days, 2 months and 3 months after treatment
3. Quality of life, measured by the quality of life score (QOL) during the treatment and at 7 days, 14 days, 21 days, 28 days, 2 months and 3 months after treatment

Overall study start date
01/02/2018

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Subjects voluntarily signed the informed consent
2. Patients suffering from chronic postherpetic neuralgia aged from 18 to 80 regardless of gender
3. Moderate to severe pain, VAS> 4 points or more, or burst pain> 3 times/day
4. Patients can follow the drug dose and follow-up plan
5. Patients can describe the symptoms, no serious infection, respiratory insufficiency and has the ability to cooperate
6. Non-allergic persons
7. No drug abuse or drug addiction
8. Non-lactating, non-pregnant women, subjects who did not have a pregnancy plan within 1 month after the test
9. Patients did not participate in a drug test within 3 months before this test (including the test drug)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
78

Total final enrolment
78

Key exclusion criteria
1. Researchers think that there is any reason participant should be excluded
2. In poor situation, severe systemic infection or respiratory dysfunction and uncooperative
3. Suffering from severe respiratory system, cardiovascular system diseases, liver and kidney dysfunction, cancer
4. Patients who are allergic to diazepam or other benzodiazepines
5. Patient who has or a history of drug abuse
6. Breastfeeding, gestational women or subjects who do not have a pregnancy plan within 1 month after the test

7. Patients who participated in a drug trial within 3 months before this trial
8. Patients does not meet the inclusion criteria

Date of first enrolment
01/02/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
China

Study participating centre
Pain Management Department, Xinhua Hospital affiliated to Shanghai Jiaotong University, School of Medicine
Shanghai
China
200092

Study participating centre
Pain Management Centre, Xinhua Hospital affiliated with Shanghai Jiaotong University school of medicine
No 1665 Kongjiang Road, Yangpu District
Shanghai
China
200092

Sponsor information

Organisation
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine)

Sponsor details
No 1665
Kongjiang Road
Yangpu District
Shanghai
China
SH 21

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/04dzvks42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine)

Results and Publications

Publication and dissemination plan
The clinical trial will be finished in July 2019, and the paper will be finished and submitted to an appropriate journal in December 2019.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/05/2024	30/05/2024	Yes	No