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The effects of oral administration of bulleyaconitine A in postherpetic neuralgia

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/11/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/11/2018	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Postherpetic neuralgia is lasting neuropathic 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. Bulleyaconitine A is an analgesic drug isolated from Aconitum plants. It was found that bulleyaconitine A could block pain-related sodium channels, producing strong analgesic and anti-inflammatory effects. The aim of this study is to assess the effects of bulleyaconitine A 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 bulleyaconitine A to take orally three times a day for 28 days. Those in group 2 are given a pIacebo (dummy drug). The basic treatment is oral Gabapentin three times a day. 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 possible benefit is that the participants could get pain relief and bulleyaconitine A for free. The possible risks are side effects of bulleyaconitine A such as dizziness and palpitation.

Where is the study run from?
1. Pain Management Department, Xinhua Hospital affiliated to Shanghai Jiaotong University, School of Medicine Shanghai (China)
2. Pain Management Department, Qinghai Provincial People's Hospital (China)
3. Pain Management Department, Yueyang Hospital affiliated to Shanghai University of Traditional Chinese Medicine (China)
4. Pain Management Department, the Second Affiliated Hospital of Kunming Medical University (China)

When is the study starting and how long is it expected to run for?
June 2018 to April 2020

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
XINHUA2018-03

Study information

Scientific Title
Clinical study of effects of oral administration of bulleyaconitine A in postherpetic neuralgia

Study objectives
1. Oral administration of bulleyaconitine A is effective and safe when administered for postherpetic neuralgia patients.
2. Treatment of oral administration of bulleyaconitine A can improve the quality of life of 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, 19/09/2018, ref: XHEC-C-2018-011-3

Study design
Multi-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
120 participants are randomly allocated to two groups using a random number table for randomization. Those in group 1 (n=60) are given bulleyaconitine A 0.4 mg t.i.d. orally for 28 days. Those in group 2 (n=60) are given placebo. The basic treatment is oral administration of Gabapentin 0.3 g 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)
Bulleyaconitine A

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 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
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
01/06/2018

Completion date
01/04/2020

Eligibility

Key inclusion criteria
1. Subjects voluntarily signed the informed consent
2. Patients suffering from 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

Sex
Both

Target number of participants
120

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 bulleyaconitine A

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
01/10/2018

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
China

Study participating centre
Pain Management Department, Xinhua Hospital affiliated to Shanghai Jiaotong University, School of Medicine Shanghai
No 1665 Kongjiang Road, Yangpu District
Shanghai
China
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Study participating centre
Pain Management Department, Qinghai Provincial People's Hospital
No. 2 Gonghe Road, Chengdong District
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Study participating centre
Pain Management Department, Yueyang Hospital affiliated to Shanghai University of Traditional Chinese Medicine
No. 110 Gan he road, Hongkou District
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Study participating centre
Pain Management Department, the Second Affiliated Hospital of Kunming Medical University
374 Burma Road

Kunming, Yunnan
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Sponsor information

Organisation
Xinhua Hospital affiliated with Shanghai Jiaotong University School of Medicine

Sponsor details
No 1665 Kongjiang Road
Yangpu District
Shanghai
China
200082

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 paper will be finished and submitted to an appropriate journal in 01/10/2020.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other