

The effects of oral administration of bulleyaconitine A in postherpetic neuralgia

Submission date 09/11/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/11/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 21/11/2018	Condition category Nervous System Diseases	☐ Individual participant data ☐ 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 placebo (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

Prof Ke Ma

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Multi-center double-blinded randomized controlled clinical study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

200082

Study participating centre

Pain Management Department, Qinghai Provincial People's Hospital

No. 2 Gonghe Road, Chengdong District

Xining, Qinghai

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Study participating centre

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Chinese Medicine**

No. 110 Gan he road, Hongkou District

Shanghai

China

200080

Study participating centre

Pain Management Department, the Second Affiliated Hospital of Kunming Medical University

374 Burma Road

Kunming, Yunnan

China

650101

Sponsor information

Organisation

Xinhua Hospital affiliated with Shanghai Jiaotong University School of Medicine

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

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