

# Yi-Qi-Pin-Chuan granules: a Chinese medicine for treatment of acute asthma

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|--|---|--|
| <b>Submission date</b><br>27/06/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>29/07/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>02/07/2018       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## Study information

**Scientific Title**  
Chinese herbs in treatment of acute asthma: a multicentre randomised, double-blind, placebo-controlled trial

**Study objectives**

Traditional Chinese medicine has been widely used in treatment of acute asthma in China, but it is based on clinical experience rather than the evidence of randomised controlled trials. Since the introduction of traditional Chinese medicine to the world, there have been many debates regarding a role for herbal medicines in the therapy of asthma.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Medical Ethics Committee of West China Hospital at Sichuan University, 25/05/2010

### **Primary study design**

Interventional

### **Study design**

Multicentre randomised double-blind placebo-controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Mild to moderate asthma in acute exacerbation

### **Interventions**

Chinese herbs arm: Chinese herbs and beta-2-agonists (salbutamol), systemic steroids (0.5 - 1 mg/kg) if necessary.

Placebo arm: placebo and beta-2-agonists (salbutamol), systemic steroids (0.5 - 1 mg/kg) if necessary.

Period of treatment: 7 days - there is no follow-up period.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Yi-Qi-Pin-Chuan granules

### **Primary outcome(s)**

The number of patients with use of systemic steroids and steroid dose, evaluated at days 4 and 8

### **Key secondary outcome(s)**

1. The number of patients with hospital admissions, evaluated at days 4 and 8
2. The number of puffs of beta agonists (salbutamol), recorded in asthma diary by the patient
3. Lung functions (PEF), assessed at hours 0, 2, 4, 6, 8, 10, 12 after recruitment, and in morning and evening every day during 7 days of treatment

### **Completion date**

31/12/2010

## Eligibility

### Key inclusion criteria

1. Mild to moderate asthma in acute exacerbation
2. Male and female patients between 15 and 75 years
3. Within 72 hours of onset of acute asthma
4. Ability to provide written informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

1. Use of systemic steroids or immunosuppressive agents within one month before recruitment, or history of life-threatening asthma requiring treatment with intubation and mechanical ventilation
2. Maintenance therapy with symbicort, or rescue therapy with formoterol or anticholinergic agents
3. Allergies to any components Yi-Qi-Pin-Chuan granule, as Chinese medicine
4. Current alcoholism or drug abuse
5. Lung diseases other asthma
6. Severe diseases of cardiovascular, hepatic, renal, central nervous system, haematopoietic system cancer
7. Significant medical illness (other than asthma) that is not stable
8. History of respiratory tract infection within the previous 6 weeks
9. Pregnancy or breastfeeding
10. The inability to understand and complete this study
11. Peptic ulcer or gastrointestinal haemorrhage
12. Intolerance to beta-2-agonists or steroids

### Date of first enrolment

15/07/2010

### Date of final enrolment

31/12/2010

## Locations

### Countries of recruitment

China

**Study participating centre**  
**Sichuan University**  
Chengdu  
China  
610041

## Sponsor information

**Organisation**  
West China Hospital at Sichuan University (China)

**ROR**  
<https://ror.org/007mrxy13>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Ministry of Education of the People's Republic of China (China) - Doctoral Fund (ref: 20070610155)

**Alternative Name(s)**  
, Министерство образования Китайской Народной Республики, , Bildungsministerium der Volksrepublik China, Ministry of Education of China, Ministry of Education, The People's Republic of China, Ministry of Education of the Central People's Government, State Education Commission, MOE

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
China

**Funder Name**  
National Natural Science Foundation of China (China) (ref: 30971326 and 30901907)

### Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

China

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/2018   |            | Yes            | No              |