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

Submission date	Recruitment status	[_] Prospectively registered
27/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2018	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Multicentre randomised double-blind placebo-controlled trial

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

Secondary outcome measures
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

Overall study start date
15/07/2010

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

Age group
Adult

Sex
Both

Target number of participants
240

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)

Sponsor details
c/o Gang Wang
Pneumology Group
Department of Integrated Traditional Chinese and Western Medicine
Chengdu
China
610041

Sponsor type
University/education

Website
http://www.scu.edu.cn/en/index.htm

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 Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/07/2018		Yes	No