ISRCTN66285433 https://doi.org/10.1186/ISRCTN66285433

Effect of obesity on asthma outcomes in acute exacerbation

Submission date 17/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/08/2010	**Overall study status** Completed	
Last Edited 12/08/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gang Wang

Contact details
Pneumology Group
Department of Integrated Traditional Chinese and Western Medicine
Sichuan University
Chengdu
China
610041

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of obesity on asthma outcomes in acute exacerbation: a multicentre interventional cohort study

Study objectives
The prevalence of both obesity and asthma is increasing throughout the Western world and increased body mass index (BMI) may be a risk factor for the development of asthma. Recent studies have indicated that obese subjects with asthma report greater resistance to therapy and poorer asthma control than normal-weight subjects with asthma. However effect of obesity on asthma outcomes in acute exacerbation remains unclear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of West China Hospital at Sichuan University approved on the 21st June 2010.

Study design
Multicentre interventional single-arm cohort study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mild to moderate asthma in acute exacerbation

Interventions
According to Chinese cut-off criteria of obesity, the subjects with asthma are divided into four groups which are the underweight group with BMI less than 18.5 kg/m2, the normal group with BMI between 18.5 and 23.9 kg/m2, the overweight group with BMI between 24.0 and 27.9 kg /m2, and the obese group with BMI greater than 28.0 kg/m2.

Interventions for all groups: beta-2-agonists (salbutamol), systemic steroids (0.5 - 1 mg/kg) if necessary.

Period of treatment: 7 days, no follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The number of patients with use of systemic steroids and steroid dose, and the number of patients with hospital admission, which are evaluated at days 4 and 8.

Secondary outcome measures
1. The number of puffs of beta agonists (salbutamol) recorded in asthma diary by the patient himself every day during 7-day study
2. Lung functions (PEF), which are assessed at hours 0, 2, 4, 6, 8, 10, 12 after recruitment, and in morning and evening every day during 7-day of treatment

Overall study start date
30/07/2010

Completion date
30/06/2011

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
2000

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. Current alcoholism or drug abuse
4. Lung diseases other asthma

5. Severe diseases of cardiovascular, hepatic, renal, central nervous system, haematopoietic system cancer
6. Significant medical illness (other than asthma) that is not stable
7. History of respiratory tract infection within the previous 6 weeks
8. Pregnancy or breast-feeding
9. The inability to understand and complete this study
10. Peptic ulcer or gastrointestinal haemorrhage
11. Intolerance to beta-2-agonists or steroids

Date of first enrolment
30/07/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
China

Study participating centre
Pneumology Group
Chengdu
China
610041

Sponsor information

Organisation
West China Hospital at Sichuan University (China)

Sponsor details
Guoxue street No. 37
Chengdu
China
610041

Sponsor type
Hospital/treatment centre

Website
http://eng.cd120.com/

ROR
https://ror.org/007mrxy13

Funder(s)

Funder type
Government

Funder Name
Doctoral Fund of Ministry of Education of China (China) (ref: 20070610155)

Funder Name
National Natural Science Foundation of China (China) (ref: 30971326; 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