

Effect of obesity on asthma outcomes in acute exacerbation

Submission date 17/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/08/2010	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

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

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

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. 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)

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 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