Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	5 September 2016
Main ID:	NCT02883582
Date of registration:	15/08/2016
Prospective Registration:	Yes
Primary sponsor:	Shanghai Asclepius Meditec Inc.
Public title:	Adjuvant Therapy for Severe Asthma by an Oxyhydrogen Generator With Nebulizer
Scientific title:	Adjuvant Therapy for Severe Asthma by an Oxyhydrogen Generator With Nebulizer: A Multi-centric, Randomized, Parallel-control and Double-blinded Clinic Study on Effectiveness and Safety
Date of first enrolment:	August 2016
Target sample size:	150
Recruitment status:	Recruiting
URL:	https://clinicaltrials.gov/show/NCT02883582
Study type:	Interventional
Study design:	Allocation: Randomized, Endpoint Classification: Safety/Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Treatment
Phase:	N/A

Countries of recruitment

China

Contacts

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Key inclusion & exclusion criteria

Inclusion Criteria:

1. Age range: =18 years old but =65 years old; sex unlimited;

2. The subjects were required to be suffered with asthma for 6 months at least by clinical diagnosis by the respirologist based on the international standards (GINA2012).There was the support of one of the following objective evidences in screening and treatment or five years before the treatment:

- It was the positive reaction in the methacholine provocative test (for the patients not applied with inhaled corticosteroid (ICS) were required at PC20<8mg/mL and PD20<0.7mg; for the patients applied with ICS were required at PC20<16mg/mL or PD20<1.4mg);

- The airway reversibility test, with a positive reaction, was defined as?FEV1.0% at a basis FEV1.0=200mL at 30 minutes after 400μgsalbutamol aerosol (mist-storing bottle might be used deliberately) was inhaled; ? The peak expiratory flow (PEF) aberration rate>20% (that is, the difference or average value of maximum and minimum PEFs times 100); it was measured for seven days successively;

- The reaction record after asthma maintenance treatment for one course of treatment (e.g. four weeks) (defined as ?FEV1.0 and its absolute value=200mL);

3. According with severe asthma diagnosis: The drug therapy was required for Level-4 and 5 asthma according to GINA Guide in the past year (The large dose of ICS combined LABA or leukotriene modifier/theophyline), or the systemic corticosteroid treatment lasted at =50% of the time to prevent from the "uncontrollable" asthma; or the "uncontrollable" asthma still occurred even if in above treatment. The uncontrollable asthma should meet one of the following requirements at least:

- Symptom control difference: ACQ>1.5, and ACT<20 (or "Non-good control" in GINA Guide);

- Frequent severe attack: Receiving systemic corticosteroid treatment for more than twice in the past year (over three days each time); ? Serious attack: Hospitalizing once in ICU or mechanical ventilation at least in the past year; ? Airway limitation: After bronchodilator was stopped properly, FEVI.0%<80% (FEV/FVC decreased to be less than lower limit of the normal value). The controlled asthma deteriorated at the decrement of above large dose ICS or systemic corticosteroid (or combined biologic agent);

4. The subjects or their legal agents could understand the trial objectives, demonstrating the compliance to the trail scheme, and signed the Informed Consent Form.

Exclusion Criteria:

1. The subjects at a body mass index>38kg/m2, or a weight<40kg;

2. The subjects' smoking amount>10 packages times the year number (e.g. number of cigarettes × the number of years for smoking/20);

3. Based on clinical interview, experience or screening inspection results, the subjects should participate in this trial improperly if the doctor responsible for the trial believed there was risk when they participated in the trial, or the research results were affected;

4. The subjects who had the recreational drug abuse history or other allergic history, but the doctor responsible for the trial believed these subjects limited by the history could participated in the trial;

5. The women subjects who were in the pregnancy or suckling period, or six weeks at least after delivery, or stopped breastfeeding for six weeks. If the women subjects were found to be pregnant in receiving one inspection, then, the inspection data for this item should be rejected in analysis;

6. The subjects ever participated in the study on a new drug or any other drugs, and were within 3 months for the first administration, or every participated in one research involved in invasive operation within 3 months. Any research evaluation should be put off to three months later in the first administration or invasive operation when they participated in the research. It was approved by the steering committee if the subjects participating in other researches were included in trial groups or continued participating in this research;

7. The investigator believed the subjects showed the risk of non-compliance with research procedures;

8. The subjects had the mental disease history resulting in loss of active ability in the recent period;

9. The following disease history or evidences demonstrated within two weeks in baseline assessment that the subjects suffered upper or lower respiratory infections or related symptoms (including common cold) (the assessment should be put off);

10. The subject changed the asthmatic drugs within four weeks before the screening;

11. The subject suffered the asthma attack in the month prior (administered with systemic corticosteroid or temporarily increasing oral corticosteroid at three days of stable base dose at least);

12. Other important diagnoses possibly similar to asthma or complicated asthma, especially respiratory dysfunction, panic attack and evident social psychological problems (if these diagnoses were seen as the patient's main symptoms rather than the symptoms except severe asthma);

13. Other severe primary pulmonary diseases, especially pulmonary embolism, pulmonary hypertension, interstitial pulmonary disease and lung cancer;

14. The subjects with emphysema and bronchiectasis should be excluded only when these diagnoses are considered as their main symptoms rather than other symptoms except severe asthma;

15. The subjects who were diagnosed with other chronic inflammatory diseases (inflammatory bowel disease, rheumatoid arthritis) except asthma.

Age minimum: 18 Years
Age maximum: 65 Years
Gender: Both

Health Condition(s) or Problem(s) studied

Asthma

Intervention(s)

Device: oxyhydrogen

Device: oxygen

Primary Outcome(s)

differentials from Mini Asthma Quality of life questionnaire (Mini AQLQ) [Time Frame: at 3 months]

Secondary Outcome(s)

differentials from renal function examination [Time Frame: at 3 months]

differentials from Baseline in Serum interleukin-4(IL - 4) [Time Frame: at 3 months]

differentials from electrolyte test [Time Frame: at 3 months]

differentials from number of asthma acute attacks [Time Frame: at 3 months]

differentials from Baseline in Serum interleukin-8(IL - 8) [Time Frame: at 3 months]

differentials from Baseline in Serum tumor necrosis factor-a(TNF-a) [Time Frame: at 3 months]

differentials from blood routine examination [Time Frame: at 3 months]

differentials from liver function examination [Time Frame: at 3 months]

differentials from asthma control questionnaire [Time Frame: at 3 months]

differentials from Baseline in Serum interleukin-13(IL - 13) [Time Frame: at 3 months]

differentials from airway resistance measurement [Time Frame: at 3 months]

differentials from asthma control test (ACT) [Time Frame: at 3 months]

differentials from induced sputum test [Time Frame: at 3 months]
differentials from pulmonary function [Time Frame: at 3 months]
differentials from 12-lead ECG test [Time Frame: at 3 months]
differentials from Special allergens [Time Frame: at 3 months]
differentials from serum C reactive protein (CRP) [Time Frame: at 3 months]
differentials from routine urine test [Time Frame: at 3 months]
differentials from Baseline in Serum interleukin-17(IL - 17) [Time Frame: at 3 months]
differentials from Baseline in Serum interleukin-5(IL - 5) [Time Frame: at 3 months]
differentials from Baseline in Serum interleukin-6(IL-6) [Time Frame: at 3 months]
differentials from number of uses of first-aid drugs [Time Frame: at 3 months]
differentials from Peak Expiratory Flow (PEF) daily aberration rate [Time Frame: at 3 months]
differentials from urine pregnancy test for fertile women [Time Frame: at 3 months]

Secondary ID(s)

QLZhang

Source(s) of Monetary Support

Please refer to primary and secondary sponsors

Secondary Sponsor(s)

The First Affiliated Hospital of Guangzhou Medical University
The Second Hospital of Hebei Medical University
West China Hospital
Second Affiliated Hospital of Guangzhou Medical University
Tianjin Medical University General Hospital

Ethics review

Results

Results available:
Date Posted:
Date Completed:
URL: