## 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.*

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| **Register:** | ClinicalTrials.gov |
| **Last refreshed on:** | 12 December 2020 |
| **Main ID:** | NCT02850185 |
| **Date of registration:** | 22/07/2016 |
| **Prospective Registration:** | Yes |
| **Primary sponsor:** | Shanghai Asclepius Meditec Inc. |
| **Public title:** | Adjuvant Therapy for Severe COPD Patients in the Stable Phase by an Oxyhydrogen Generator With Nebulizer |
| **Scientific title:** | Adjuvant Therapy for Severe COPD Patients in the Stable Phase by an Oxyhydrogen Generator With Nebulizer: A Multi-centric, Randomized, Parallel-control and Double-blinded Clinic Study |
| **Date of first enrolment:** | July 15, 2016 |
| **Target sample size:** | 170 |
| **Recruitment status:** | Recruiting |
| **URL:** | https://clinicaltrials.gov/show/NCT02850185 |
| **Study type:** | Interventional |
| **Study design:** | Allocation: Randomized. Intervention model: Parallel Assignment. Primary purpose: Other. Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor). |
| **Phase:** | N/A |

## Countries of recruitment

China

## Contacts

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|---|---|---|
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## Key inclusion & exclusion criteria

Inclusion Criteria:

1. It conforms to the diagnostic criteria of chronic obstructive pulmonary diseases (COPD): (PFT)The percentage of forced expiratory volume in forced vital capacity in one second after inhaling vasodilator (FEV1 / FVC% < 70%);

2. Classification of COPD severity by pulmonary function: The criterion for this study is Severe: FEV1/FVC<0.70, and FEV1< 50% expected value after pulmonary function was examined by taking bronchodilator.

3. More than 40 years old and have normal ability to judge independently; men and women are not limited;

4. Living in the vicinity of the test centre in the past six months; -

Exclusion Criteria:

- 1) Those who have acute exacerbation in the past 4 weeks; 2) Lung disease history: Excluding the history of other lung diseases except combined COPD, such as combined pulmonary tuberculosis and diffuse pan-capillary bronchiolitis, pneumonia, pneumothorax, pleural effusion, pulmonary embolism, etc.

3) Those who suffer infectious diseases such as hepatitis A, hepatitis B, AIDS and tuberculosis or connective tissue diseases in the active period; 4) Those who suffer high fever, as well as various local or systemic infections (including respiratory, urinary and reproductive system, digestive system, sepsis, etc.), severe infection, especially lung infection found by CT examination; 5) Those who have limited ability to understand and poor compliance; do not have the legal capacity or limited legal capacity; participated in other clinical trials in the first 3 months when they were included in the groups; mental or physical disability; 6) Those who were difficult to make an exact evaluation on safety and effectiveness of products; 7) The women in pregnancy and lactation, as well as the women at childbearing age who don't agree to take effective contraceptive measures during the study period; 8) Those who have abnormal heart function and thrombophlebitis; 9) Those who are known and can't stand the oxygen and hydrogen inhalation; 10) Those who are suffered from primary diseases in important visceral organs and systems, such as stroke, severe hypertension, gastric ulcer, uncontrolled diabetes, malignant tumor, liver and kidney failure, and severe heart disease history (acute myocardial infarction, congestive heart failure and other heart diseases in the acute phase); 11) Cancer in progressive stage as well as undetermined masses found in the treatment; 12) Those who have one or more lobectomy history; 13) Those who are suspected to have or really have alcohol and drug abuse history; 14) Those whose AST and ALT=120U/L, Ccr=50ml/min; who have shock or unstable hemodynamics; 15) Those who are considered not to participate in clinical trials by

the investigators.

Age minimum: 40 Years
Age maximum: N/A
Gender: All

**Health Condition(s) or Problem(s) studied**

COPD

**Intervention(s)**

Device: Oxygen

Drug: Conventional treatment

Device: oxyhydrogen

**Primary Outcome(s)**

Change from Baseline in dyspnea index score (mMRC score) at 3 months [Time Frame: baseline and 3 months]

**Secondary Outcome(s)**

Change from Baseline in Residual volume(RV) at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in Serum interleukin-6(IL-6) at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in carbon dioxide arterial tension (PaCO2) at 3 months [Time Frame: baseline and 3 months]

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

Change from Baseline in Arterial oxygen tension (PaO2) at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in mean maximum expiratory flow(MMEF) at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in Six minute walk distance at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in Pulmonary artery pressure measured by heart color Doppler ultrasound at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in First second forcibly expiration quantity(FEV1) at 3 months [Time Frame: baseline and 3 months]

number of participants with adverse events [Time Frame: up to 3 months]

Change from Baseline in Forcibly vital capacity(FVC) at 3 months [Time Frame: baseline and 3 months]

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

Change from Baseline in Serum 8-isoprostane at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in St George's respiratory questionnaire (SGRQ score) at 3 months [Time Frame: baseline and 3 months]

Change from Baseline in Serum malondialdehyde (MDA) at 3 months [Time Frame: baseline and 3 months]

**Secondary ID(s)**

ZZheng

**Source(s) of Monetary Support**

Please refer to primary and secondary sponsors

**Secondary Sponsor(s)**

West China Hospital

The First Affiliated Hospital of Guangzhou Medical University

Second Affiliated Hospital of Guangzhou Medical University

Tianjin Medical University General Hospital

The Second Hospital of Hebei Medical University

**Ethics review**

**Results**

**Results available:**

**Date Posted:**

**Date Completed:**

**URL:**