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:	21 November 2016
Main ID:	NCT02961387
Date of registration:	02/11/2016
Prospective Registration:	Yes
Primary sponsor:	Guangzhou Institute of Respiratory Disease
Public title:	A Clinical Trial on Effectiveness and Safety of Hydrogen Generator to Treat Dyspnea for the Patients With Tracheal Stenosis: A Randomized, Double-blind and Single-center Clinical Study
Scientific title:	A Clinical Trial on Effectiveness and Safety of Inhaling Hydrogen-oxygen to Decreases Inspiratory Effort for the Patients With Tracheal Stenosis: A Randomized, Double-blind and Single-center Clinical Study
Date of first enrolment:	November 2016
Target sample size:	50
Recruitment status:	Recruiting
URL:	https://clinicaltrials.gov/show/NCT02961387
Study type:	Interventional
Study design:	Allocation: Randomized, Endpoint Classification: Safety/Efficacy Study, Intervention Model: Crossover Assignment, Masking: Double Blind (Subject, Caregiver, Investigator), Primary Purpose: Treatment
Phase:	N/A

Countries of recruitment

China

Contacts

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Key inclusion & exclusion criteria

Inclusion Criteria:

1. Aged from 18 to 65;

2. Diagnosed moderate/severe tracheal stenosis by chest CT and/or bronchoscopy;

3. Difficulty breathing symptoms

4. Agree to participate in this trial and sign the informed consent form.

Exclusion Criteria:

1. Those who were suffered from respiratory failure or more severe caused by dyspnea;

2. Combined other serious systemic diseases (severe arrhythmia, acute myocardial ischemia, uncontrollable hypertension crisis, active gastric ulcer, uncontrolled diabetes, renal failure, blood system diseases or coagulation dysfunction);

3. Those who were suffered from severe mental illness or could not take care of themselves;

4. Pregnant or lactating women;

5. Those who could not understand the trial procedures and correctly the trial equipment;

6. Those who participated in other clinical trials in the first 3 months before the screening date.

Quit criteria

1. The subjects requiring emergency intubation or other intervention or surgical treatment due to worsened tracheal stenosis;

2. Subjects who had severe adverse events during treatment;

3. Subjects who did not want to continue to participate in the trial;

4. The subjects who were necessarily terminated for the trial by the investigators.

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

Health Condition(s) or Problem(s) studied

Tracheal Stenosis

Intervention(s)

Device: Hydrogen generator treatment

Device: Oxygen-making machine treatment

Primary Outcome(s)

Change in sRMSdi/para/sc, RMSdi, Pdi& MIP from baseline after inhalation by bench study. [Time Frame: Baseline, 10min, 20min, 30min, 40min, 50min, 90min and 150min]

Secondary Outcome(s)

Change in cough waves from baseline when inhaling [Time Frame: Baseline, Inhaling.]

Change in symptom of dyspnea from baseline after inhalation. [Time Frame: Baseline, 10min, 20min, 30min, 40min, 50min, 90min and 150min]

Change in Borg score for dyspnea after inhalation. [Time Frame: Baseline, 10min, 20min, 30min, 40min, 50min, 90min and 150min]

Change in impulse oscillometry variables(R5,R20,X5,AX,RF) as change from baseline when inhaling. [Time Frame: Baseline and inhaling]

Change in PaO2, PaCO2, PH& HCO3- after inhalation [Time Frame: Baseline and 150min]

Change in signs(BR, HR, BP, el) from baseline after inhalation [Time Frame: Baseline, 10min, 20min, 30min, 40min, 50min, 90min and 150min]

Grades of airway stenosis by bronchoscopy [Time Frame: baseline]

FEV1 & FVC [Time Frame: Baseline]

Secondary ID(s)

TS20160801

Source(s) of Monetary Support

Please refer to primary and secondary sponsors

Secondary Sponsor(s)

Ethics review

Results

Results available:

Date Posted:

Date Completed:

URL: