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:	12 December 2020
Main ID:	NCT02765295
Date of registration:	03/05/2016
Prospective Registration:	Yes
Primary sponsor:	Guangzhou Institute of Respiratory Disease
Public title:	Efficacy and Safety of Hydrogen Inhalation on Bronchiectasis: A Randomized, Multi-center, Double-blind Study HYBRID
Scientific title:	Efficacy and Safety of Hydrogen Inhalation on Bronchiectasis (HYBRID): A Randomized, Multi-center, Double-blind, Parallel-group Study
Date of first enrolment:	June 1, 2016
Target sample size:	120
Recruitment status:	Recruiting
URL:	https://clinicaltrials.gov/show/NCT02765295
Study type:	Interventional
Study design:	Allocation: Randomized. Intervention model: Parallel Assignment. Primary purpose: Treatment. Masking: Double (Participant, Investigator).
Phase:	N/A

Countries of recruitment

China

Contacts

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Key inclusion & exclusion criteria

Inclusion Criteria:

- Out-patients of either gender, ex- or never-smokers, aged between 18 and 75 years

- Clinically stable bronchiectasis, defined as respiratory symptoms and lung function parameters not exceeding normal daily variations and no acute upper respiratory tract infections for 4 consecutive weeks

- Patients with a history of 2 or more bronchiectasis exacerbations (BEs) within the previous 2 years

Exclusion Criteria:

- Other unstable concomitant systemic illnesses (i.e. coronary heart disease, recent cerebral stroke, severe uncontrolled hypertension, active gastric or duodenal ulcer, uncontrolled diabetes, malignancy, hepatic or renal dysfunction)

- Concomitant asthma, allergic bronchopulmonary aspergillosis, or active tuberculosis

- Concomitant chronic obstructive pulmonary disease as the predominant diagnosis

- Treatment with inhaled, oral or systemic antibiotics within 4 weeks

- Type 2 respiratory failure needing oxygen therapy or non-invasive mechanical ventilation

- Females during lactation or pregnancy

- Poor understanding or failure to properly operate the instrument

- Participation in other clinical trials within 3 months.

Age minimum: 18 Years
Age maximum: 75 Years
Gender: All

Health Condition(s) or Problem(s) studied

Oxidative Stress

Bronchiectasis

Acute Exacerbation of Bronchiectasis

Intervention(s)

Device: medical ultrasonic hydrogen/oxygen nebulizer (MUNHO)

Device: Medical molecular mesh oxygen generator

Primary Outcome(s)

Frequency of bronchiectasis exacerbations (BEs) within 12 months [Time Frame: up to 12 months (1 year)]

Secondary Outcome(s)

Changes in CRP levels at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Changes in quality of life assessed by using Quality-of-Life Questionnaire--Bronchiectasis (QoL-B) at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Changes in sputum oxidant (hydrogen peroxide, reactive oxygen species) levels at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Changes in serum oxidant (hydrogen peroxide, reactive oxygen species) levels at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Changes in spirometry, including FEV1, FEV1/FVC ratio and MMEF at each visit following randomization as compared with baseline [Time Frame: baseline, month 1, month 3, month 6, month 9 and month 12]

Changes in sputum antioxidants levels (catalase, superoxide dismutase and total antioxidant capacity) at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Changes in serum antioxidants levels (catalase, superoxide dismutase and total antioxidant capacity) at month 6 and 12 as compared with baseline [Time Frame: baseline, month 6 and month 12]

Time to the first bronchiectasis exacerbations (BEs) within 12 months [Time Frame: up to 12 months]

Secondary ID(s)

GWJ-2015-H2

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: