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Effects of Xuanfei Baidu granules in patients with acute exacerbation of a progressive, long-term lung condition

Submission date 06/07/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 13/07/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/07/2026	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a common long-term lung condition that causes breathing difficulties. When COPD suddenly worsens (called an acute exacerbation, or AECOPD), patients often need hospital admission and standard Western medical treatment. Even with standard care, many people suffer from lingering breathing symptoms that take a long time to clear up.

Xuanfei Baidu granules is a traditional Chinese herbal medicine mixture shown in earlier lab research to calm lung inflammation. This study's main goal is to test whether adding these granules to routine hospital treatment speeds up recovery from AECOPD symptoms. It also plans to check how well the treatment improves patients' daily breathing-related quality of life, how much hospital medical resources are used, and whether the herbal medicine is safe to take. The study will also look at whether the treatment works better for people with mild/moderate COPD versus those with severe COPD.

Who can participate?
Adult patients aged 40 to 85 years old admitted to hospital for a sudden COPD flare-up (AECOPD).

What does the study involve?
This is a hospital-based research trial that will split eligible patients into two equal groups by random chance (like flipping a coin):
Control group: Receive standard hospital Western medicine for AECOPD following global COPD guidelines. This includes oxygen, regular inhaled nebuliser treatment, steroid tablets/injections, targeted antibiotics, and supportive care such as mucus-thinning drugs and blood clot prevention.
Experimental group: Get exactly the same standard Western hospital treatment as the control group, plus Xuanfei Baidu Granules (one sachet three times per day for 7 full days).
No participants can use other Chinese herbal injections, certain breathing drugs (theophylline), or other oral Chinese cough remedies during the study.

The study will track all participants for 14 days after they join the trial. Research staff will record how long it takes for breathing symptoms to settle fully, complete standard breathing symptom questionnaires, take blood tests and check blood oxygen/carbon dioxide levels, and log how long patients use nebulisers, steroids and antibiotics. The study will also record total hospital costs and monitor all side effects throughout the trial. All collected patient data will be analysed by a separate research team who will not know which treatment group each patient belongs to.

The full recruitment, treatment and follow-up period will run until 120 eligible patients have completed their 14-day study monitoring. Each individual patient's participation lasts 14 days from the day they are randomly assigned to a treatment group, with the herbal medicine course limited to the first 7 days of their hospital stay.

What are the possible benefits and risks of participating?
Possible benefits:
Participants may experience faster relief from COPD flare-up breathing symptoms if they are placed in the herbal medicine group.
All participants will receive fully standardised, guideline-compliant hospital care for their COPD worsening.
Their lung symptoms, blood test results and breathing function will be closely checked by hospital respiratory specialists during admission.
Those given the herbal granules may need shorter courses of nebuliser and steroid treatment.

Possible risks:
There is no guarantee that participants will be allocated to the herbal treatment group; half of participants will only receive standard hospital care.
As with all medicines, the herbal granules could cause mild unwanted side effects (e.g. mild stomach upset). The research team will monitor all side effects closely throughout treatment.
Severe harmful reactions to the herbal medicine are thought to be rare based on prior use, but all participants will have regular physical checks and blood tests to watch for any serious issues.
Extra blood tests and questionnaires for the study will add small amounts of extra time to the hospital routine.

Where is the study run from?
The Respiratory Department of Tianjin Binhai New Area Dagang Hospital, China.

When is the study starting and how long is it expected to run for?
May 2024 to July 2026.

Who is funding the study?
The General Science and Technology Program from the Tianjin Binhai New Area Health Committee, China.

Who is the main contact?
Lead contact researcher: Dr Shubin Lv, Respiratory Department, Tianjin Binhai New Area Dagang Hospital, 83730692@qq.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Tianjin Binhai New Area Health Research Project Grant Number
2023BWKY010

Study information

Scientific Title
Efficacy of Xuanfei Baidu granules in patients with acute exacerbation of COPD: a randomized, controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/10/2023, Ethics Committee of Tianjin Binhai New Area Dagang Hospital (No. 1200, South Ring Road, Dagang Area, Binhai New District, Tianjin, 300270, China; +86-022-63109304; dgyykjk@126.com), ref: GYKY-2023-004

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Acute Exacerbation of COPD

Interventions
The Control Group received standardized comprehensive Western medicine treatment, adhering strictly to GOLD 2026 and domestic AECOPD management standards. This protocol included oxygen therapy to maintain SpO2 between 88%–92% (with early non-invasive mechanical ventilation for hypercapnia), scheduled nebulization using short-acting β_2-agonists combined with anticholinergic agents every 2–4 hours, systemic corticosteroids (prednisone 40 mg/day orally or methylprednisolone 40 mg/day intravenously for 5 days), targeted antibiotic therapy based on clinical risk stratification and sputum culture for 5–7 days, and supportive care including mucolytics, postural drainage, nutrition, and venous thromboembolism prophylaxis. The Experimental Group received the identical standardized Western medicine regimen described above, supplemented with Xuanfei Baidu Granules (1 sachet, 3 times daily for 7 days).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Xuanfei Baidu Granules

Primary outcome(s)
1. Time to clinical symptom recovery measured using an investigator-conducted clinical assessment (evaluating dyspnea relief, normalised sputum volume, and stable cough status) at randomisation (baseline) and day 14; participants who fail to meet recovery criteria by day 14 will be right-censored at day 14

Key secondary outcome(s)

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. Patients aged 40–85 years
2. Confirmed diagnosis of COPD according to GOLD 2026 guidelines, with an acute exacerbation necessitating hospitalization (defined by an acute onset of respiratory symptoms—dyspnea, increased sputum volume, or purulent sputum—exceeding daily variations)
3. GOLD classification 1–4
4. Willingness to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
85 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Respiratory failure requiring invasive mechanical ventilation
2. Concomitant diagnosis of asthma, bronchiectasis, or active pulmonary tuberculosis
3. Severe comorbidities, including unstable cardiovascular disease, malignancy, or end-stage renal/hepatic failure
4. History of severe allergic reaction to the study drug
5. Inability to comply with the 7-day treatment protocol

Date of first enrolment
01/05/2024

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Tianjin Binhai New Area Dagang Hospital

Funder(s)

Funder type

Funder Name

General Program of Science and Technology Project of Tianjin Binhai New Area Health Committee

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Chinese		07/07/2026	No	Yes
Protocol file			13/07/2026	No	No