ISRCTN17427081 https://doi.org/10.1186/ISRCTN17427081

# Using the Huangqi-Baizhu formula to manage chronic obstructive pulmonary disease

| | | |
|---|---|---|
| **Submission date** | **Recruitment status** | [_] Prospectively registered |
| 06/12/2025 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 09/12/2025 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 08/12/2025 | Respiratory | [X] Record updated in last year |

**Plain English summary of protocol**

Background and study aims

Chronic obstructive pulmonary disease (COPD) is a progressive condition characterized by recurrent exacerbations and irreversible decline in lung function. Despite the availability of standard drug treatments, high rates of hospital readmission persist, imposing a significant clinical burden. Consequently, there is an urgent need to identify effective strategies to improve patient outcomes.

In China, classical TCM formulas such as Yu–Ping–Feng and Bu–Zhong–Yi–Qi, which share the core ingredients Astragalus membranaceus (Huangqi) and Atractylodes macrocephala (Baizhu), have long been effective in clinical application. However, robust evidence regarding their impact is lacking. This study specifically defined prescriptions containing the core binary component containing only Huangqi and Baizhu as the Huangqi–Baizhu formula. The aim was to evaluate the effectiveness of this formula on patients with COPD.

Who can participate?

Participants were eligible for inclusion if they had a first hospitalization with a primary diagnosis of COPD (ICD-10 codes: J44.0, J44.1, J44.9), were aged 40 to 84 years, and had at least one outpatient follow-up within the subsequent year.

What does the study involve?

Patients were categorized into two groups based on the therapeutic regimens received during hospitalization. The treatment group consisted of patients who receive the Huangqi–Baizhu formula. The control group consisted of patients who did not received Huangqi–Baizhu formula. Both groups received routine medical treatment.

What are the possible benefits and risks of participating?

Not applicable.

Where is the study run from?

Data were extracted from the electronic medical records (EMRs) of four tertiary hospitals in China: the Affiliated Hospital of Shandong University of Traditional Chinese Medicine, the Third

Affiliated Hospital of Beijing University of Chinese Medicine, Zaozhuang Hospital of Dongfang Hospital of Beijing University of Chinese Medicine, and Qingdao West Coast New Area Hospital of Traditional Chinese Medicine.

When is the study starting and how long is it expected to run for?
The EMRs of patients covered the period from 1 January 2019 to 31 December 2024. Data collection for this study commenced on 1 November 2025, and the study is expected to conclude by 10 September 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Xiaomeng Cheng, chengxm20@163.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Xiaomeng Cheng

### Contact details
51 Anwai Xiaoguan Street, Chaoyang District
Beijing
China
100029
+86 (0)17862969002
chengxm20@163.com

# Additional identifiers

# Study information

### Scientific Title
Real-world study of the Huangqi-Baizhu formula in patients with chronic obstructive pulmonary disease

### Acronym
HBF-COPD

### Study objectives
This study aims to explore precision TCM therapies for COPD prognosis. By quantifying the specific prognostic impact of the Huangqi–Baizhu formula and thereby identifying potential therapeutic candidates for improving COPD prognosis, the study ultimately seeks to streamline therapeutic regimens.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 31/10/2025, Ethics Committee of the Affiliated Hospital of Shandong University of Traditional Chinese Medicine (Shandong Province, Ji'nan City, Lixia District, Jing Shi Road, No. 16369, Jinan, 250014, China; +86 (0)531-68616733; zyyuanjie2007@163.com), ref: 2025170KY

### Primary study design
Observational

### Secondary study design
Cohort study

### Study type(s)

### Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

### Interventions
Utilizing a Target Trial Emulation (TTE) design on real-world data (Jan 2019–Dec 2024) from four Chinese tertiary hospitals, this study evaluates HBF effect on 1-year readmission risks. To mitigate confounding from concomitant herbs, the analysis employs PCA and UMAP dimensionality reduction. De-identified EMR data—including demographics, comorbidities, and auxiliary results—are linked to identify index discharges. Patients are classified into a Treatment Group and a Control Group. Patients in the treatment group received TCM prescriptions characterized by Astragalus membranaceus (Huangqi) as the Sovereign (Jun) herb and Atractylodes macrocephala (Baizhu) as the Minister (Chen) herb. For the purpose of this analysis, these complex prescriptions were conceptually decomposed into two parts: the HBF (defined strictly as the core binary component containing only Huangqi and Baizhu) and other concomitant herbs. The Control Group did not receive HBF. Both groups received routine medical treatment.

### Intervention Type
Other

### Primary outcome(s)
1. Readmission due to acute exacerbations of chronic obstructive pulmonary disease measured using data extracted from the electronic medical records at Within 1 year

### Key secondary outcome(s)
1. All-cause readmission measured using data extracted from the electronic medical records at within 1 year

### Completion date
10/09/2026

## Eligibility

### Key inclusion criteria

1. Age 40–84 years
2. Diagnosis of COPD or AECOPD, validated by spirometry or clinical history
3. Verified survival >1 year (indicated by ≥1 outpatient record)

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
40 Years

### Upper age limit
84 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Patients admitted for reasons other than COPD (i.e., COPD was not the primary diagnosis)
2. Patients with confounding pulmonary conditions, such as lung malignant neoplasm, pulmonary tuberculosis, thoracic trauma, interstitial lung disease, or lung diseases due to external agents
3. Patients with mental disorders who are unable to cooperate with treatment
4.Patients during pregnancy and lactation
5. Patients did not use TCM throughout hospitalization
6. Patients with consecutive hospitalizations, those discharged against medical advice, transferred to other wards, or with a hospital stay of less than 3 days

### Date of first enrolment
01/11/2025

### Date of final enrolment
30/04/2026

## Locations

### Countries of recruitment
China

## Sponsor information

### Organisation

Affiliated Hospital of Shandong University of Traditional Chinese Medicine

**ROR**
https://ror.org/052q26725

**Organisation**
Third Affiliated Hospital of Beijing University of Chinese Medicine

# Funder(s)

**Funder type**

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available