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A study on the application of hufu copper bian scraping combined with acupoint application in patients with community-acquired pneumonia of phlegm-heat obstructing the lung syndrome-a randomized controlled study

Submission date
06/11/2026

Recruitment status
No longer recruiting

Registration date
10/11/2026

Overall study status
Completed

Last Edited
09/11/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Hebei Provincial Health Commission Project Number
20250957

Study information

Scientific Title
A study of phlegm-heat obstructing the lung syndrome

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/12/2023, Affiliated Hospital of Hebei University of Engineering (No. 81 Congtai Road, Congtai District, Handan City, 056002, China; +86-0310 3130866; hbgdfy2000@163.com), ref: 2026 [K]038

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Community-acquired pneumonia (CAP), specifically non-severe CAP in adults with the traditional Chinese medicine syndrome of phlegm-heat obstructing the lung.

Interventions
Randomization was performed using a random number table as follows:
1. All patients were numbered according to the order of inclusion
2. Starting from any row and column of the random number table, random numbers equal to the sample size were copied in a predetermined direction (e.g., left to right, top to bottom)
3. Patients were divided directly according to the parity of the random number: odd numbers into the experimental group, even numbers into the control group
4. If the number of patients in each group was unequal, random numbers were continued to be drawn for the excess subjects in the same way until the numbers in both groups were equal

For allocation concealment:
1. The grouping sequence and allocation scheme were generated by designated researchers using a random number table
2. Personnel who were aware of the group information no longer participated in the recruitment and allocation of subsequent subjects
3. The generated random allocation table was entrusted to independent personnel not involved in this trial, and sealed, opaque envelopes were used one by one during actual allocation to ensure concealment of the allocation scheme

Control arm: Conventional Western medicine: levofloxacin sodium chloride injection 100 mL by intravenous infusion once daily (adjusted according to drug susceptibility results when available); ambroxol hydrochloride sodium chloride injection 100 mL by intravenous infusion twice daily. Treatment duration: 12 consecutive days.

Study arm: Same conventional Western medicine as the control arm, plus:
Hufu copper bian scraping: scraping along the Heart Meridian of Hand-Shaoyin, Lung Meridian of Hand-Taiyin, Large Intestine Meridian of Hand-Yangming, Sanjiao Meridian of Hand-Shaoyang, Du Meridian, and Bladder Meridian of Foot-Taiyang, and the Four Opening Points (Dazhui, Dazhu, Gaohuangshu, Shentang). Each session lasted approximately 30 minutes, once every 3 days, with 2 sessions constituting one course, over 12 days.

Herbal acupoint application: a paste made from roasted Ephedra sinica 9 g, raw Rheum palmatum 9 g, Perilla frutescens 9 g, Sinapis alba 6 g, and Mentha haplocalyx 3 g, ground into fine powder and mixed with honey, applied to Danzhong (CV17), bilateral Feishu (BL13), and bilateral Fenglong (ST40). Applied once daily for 2–4 hours each time, over 12 days.

Both groups received continuous treatment for 12 days.

The outcomes involve the Clinical Pulmonary Infection Score (CPIS) measured using CPIS, a 6-item score with a total range of 0–12 points (body temperature, blood white cell count, tracheal secretions, oxygenation index, chest X-ray infiltration, and tracheal aspirate/sputum culture); higher scores indicate more severe pulmonary infection.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pulmonary infection measured using the Clinical Pulmonary Infection Score (CPIS) at admission (baseline) and after 12 consecutive days of treatment

Key secondary outcome(s)

Completion date
10/01/2025

Eligibility

Key inclusion criteria
1. Adults diagnosed with non-severe community-acquired pneumonia (CAP) according to the Chinese Guidelines for the Diagnosis and Treatment of Adult CAP (2016 edition)
2. Meeting the traditional Chinese medicine diagnostic criteria for CAP of phlegm-heat obstructing the lung syndrome according to the Chinese Medicine Guidelines for CAP (2018 revised edition)
3. Aged 18–70 years
4. Voluntary participation with signed informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
101

Key exclusion criteria

Key exclusion criteria:
1. Pregnant or lactating women
2. Patients with severe hepatic or renal insufficiency
3. Patients with diabetes mellitus, severe skin diseases, or severe cardiovascular and cerebrovascular diseases
4. Patients with mental illness or inability to cooperate with the study
5. Patients with allergy to Chinese herbal medicine or acupoint application

Dropout/exclusion criteria:
1. Severe adverse reactions or complications preventing continuation of the study
2. Incomplete clinical data due to failure to strictly follow the study protocol for medication and examinations
3. Voluntary withdrawal from the study

Date of first enrolment
01/01/2024

Date of final enrolment
30/12/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Affiliated Hospital of Hebei University of Engineering

Funder(s)

Funder type

Funder Name
Health Commission of Hebei Province

Alternative Name(s)
Hebei Provincial Health Commission,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available