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A clinical trial to evaluate the efficacy and safety of Shufeng Jiedu capsule in acute exacerbation of chronic obstructive pulmonary disease (COPD)

Submission date
26/09/2021

Recruitment status
No longer recruiting

Registration date
07/10/2021

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. Patients with COPD commonly experience flare-ups (“acute exacerbations”) and antibiotics are often prescribed. However, only one in three flare-ups are caused by bacterial infections and are helped by antibiotics. The remaining two out of three flare-ups are caused by viruses or environmental factors and in these cases, antibiotics will not help. If you take antibiotics, you are more likely to suffer from an infection from drug-resistant bacteria in the future, so it is important to find a safe and effective way to control the symptoms of COPD flare-ups. There is evidence, based on studies conducted in China, that an herbal combination treatment called Shufeng Jiedu could help control symptoms of COPD flare-ups. We would like to know whether the herbal combination, Shufeng Jiedu, could improve symptoms, and reduce the use for antibiotics.

Who can participate?
COPD patients aged 40 years or older who with a moderate or severe hospitalized acute exacerbation of COPD will be invited to take part in this trial.

What does the study involve?
Eligible patients (participants) will be randomly allocated to SFJD plus usual care or placebo (dummy capsule) plus usual care, and SFJD (placebo) will take 4 capsules, 3 times a day for 7 days. Participants will be asked to complete a participant diary for 56 days after day of meeting discharge criteria, recording their COPD flare-up symptoms and quality of life in questionnaires and any medication they have taken for their flare-up.

What are the possible benefits and risks of participating?
It is not known whether you will have any additional benefit from taking part in this trial.

However, your participation will give important information about how best to treat people with flare-ups of their COPD.
You may experience mild side effects from taking the trial medication.

Where is the study run from?
Beijing University of Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
August 2019 to June 2024

Who is funding the study?
National Key Research and Development Project (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A multicentre, randomised, double-blind, controlled trial to evaluate the efficacy and safety of Shufeng Jiedu capsule in acute exacerbation of COPD

Study objectives
Shufeng Jiedu (SFJD) capsule will improve symptoms in people with acute exacerbation of COPD, and will therefore reduce the use for antibiotics, the duration of admission to hospital, and the risk of relapse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/09/2021, Clinical Medical Research Ethics Committee of the First Affiliated Hospital, Anhui Medical University (No.218, First Affiliated Hospital of Anhui Medical University, Jixi Road, Hefei, 230022, China; +86 (0)551-62923537; 331417268@qq.com), ref: ——PJ2021-12-31

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Interventions
Shufeng Jiedu capsule (4 capsules tid for 7 days) plus usual care will be used in the experimental group. Placebo (4 capsules tid for 7 days) plus usual care will be used in the control group. Usual care may include glucocorticoids, bronchodilators, oxygen therapy, and antibiotics.

The study consists of the baseline visit, 7 days treatment period, followed by the EOT (End-of-Therapy, day 8), and LFU (Late Follow-up: 14 days after meeting discharge criteria,28 days after meeting discharge criteria, and 56 days after meeting discharge criteria) visits.

Randomisation:
A stratified, blocked random sequence is generated by R software. Drug containers prepared by an independent pharmacy were sequentially numbered and opened sequentially. Containers were of identical appearance, tamper-proof and equal in weight.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Shufeng Jiedu capsule

Primary outcome measure
Severity of clinical symptoms is measured using the EXACT-PRO score at the end of treatment on day 8.

Secondary outcome measures
1. Clinical symptoms measured using CAT scores at end of treatment; EXACT-PRO scores and CAT scores at day of meeting discharge criteria and three follow-up time points (day of meeting discharge criteria + 14 days, day of meeting discharge criteria + 28 days, day of meeting discharge criteria + 56 days); EXACT-PRO frequency and duration of symptom-defined events, and severity of symptoms.
2. QoL measured using SGRQ and EQ-5D at end of treatment; EQ-5D scores at day of meeting discharge criteria, day of meeting discharge criteria + 14 days, day of meeting discharge criteria + 28 days, day of meeting discharge criteria + 56 days.
3. Length of stay (LOS) measured using the duration from admission to meeting discharge criteria.
4. A total dose of antibiotics measured using DDDs.
5. The frequency of recurrence of acute exacerbations of COPD during follow-up 8 weeks (including medical consultation or admission).
6. Hematologic biomarkers (full blood count, inflammation factors) absolute value and change

from baseline at end of treatment.
7. Death during hospitalization or follow-up measured using patient records
8. Safety measured using adverse event (AE) and adverse drug reaction (ADR) measured using patient records throughout the study period

Overall study start date
01/08/2019

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Diagnosis of COPD or has been diagnosed in clinical record.
2. Has a current acute exacerbation of COPD with at least one of the following:
2.1. Increased sputum purulence
2.2. Increased sputum volume
2.3. Increased breathlessness
3. The patient with moderate or severe hospitalized acute exacerbation of COPD (FEV1%: 30% to 80%).
4. Males and females 40 or more years of age.
5. Patient must provide written informed consent prior to any study-specific procedures, and willingness and ability to comply with all study procedures.

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
Planned Sample Size: 300

Key exclusion criteria
1. Severe pulmonary illness (e.g. needed mechanical ventilation treatment, or necessity for admission to ICU).
2. Patient has a primary diagnosis of bronchiectasis, lung cancer or other active chronic respiratory disease.
3. Pleural empyema (not including non-purulent parapneumonic effusions).
4. Neoplastic lung disease, cystic fibrosis, progressively fatal disease, chronic neurological disorder preventing clearance of pulmonary secretions, or life expectancy of less than or equal to 3 months.
5. Carcinoma.

6. Past or current history of epilepsy or seizure disorder.
7. Severe liver disease, haematological, or immunologic disease.
8. Severely impaired renal function (CLCR ≤30 mL/min) estimated by the Cockcroft Gault formula.
9. Evidence of immediately life-threatening disease, including, but not limited to, current or impending respiratory failure, acute heart failure, shock, acute coronary syndrome, unstable arrhythmias, hypertensive emergency, acute hepatic failure, active gastrointestinal bleeding, profound metabolic abnormalities (eg, diabetic ketoacidosis), or acute cerebrovascular events.
10. Confirmed or suspected respiratory tract infections attributable to sources other than acute exacerbation of COPD (eg, pneumonia), non-infectious causes of pulmonary infiltrates (eg, pulmonary embolism, chemical pneumonitis from aspiration, hypersensitivity pneumonia, congestive heart failure).
11. Requirement for concomitant antimicrobial or systemic antifungal therapy for any reason.
EXCEPTIONS: topical antifungal or antimicrobial therapy, a single oral dose of any antifungal for treatment of vaginal candidiasis
12. Infections or conditions requiring concomitant systemic corticosteroids.
EXCEPTION: the corticosteroid dose equivalent is less than 40 mg prednisone per day.
13. Previous treatment with an antimicrobial or corticosteroids for treatment of this acute exacerbation of COPD more than 72 hours leading up to admission.
14. Use traditional Chinese medicine as therapy for this acute exacerbation of COPD.
15. Probenecid administration within 3 days prior to initiation of the study treatment regimen or requirement for concomitant therapy with probenecid.
16. Women who are pregnant (confirmed by a urine pregnancy test) or lactating. Women of childbearing potential who are at risk of pregnancy and not using an effective form of contraception.
17. History of any hypersensitivity or allergic reaction to SFJD or composition of SFJD.
18. Hospitalization within 14 days prior to onset of symptoms.
19. Previously been recruited into another drug trial within the last 6 weeks.
20. Involvement in the planning and/or conduct of the study (applies to Jiren staff and their representatives).

Date of first enrolment
01/11/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
China

Study participating centre
The first affiliated hospital of Anhui medical university
No.218, Jixi road
Hefei
China
230022

Study participating centre
Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine
No.5, Haiyuncang
Dongcheng District
Beijing
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100700

Study participating centre
Shanghai Fifth People's Hospital of Fudan University
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University/education

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ROR
https://ror.org/05damtm70

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology of the People's Republic of China

Alternative Name(s)
Chinese Ministry of Science and Technology, Ministry of Science & Technology, People Republic of China, , Ministry of Science and Technology (China), State Science and Technology Commission, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/09/2023	02/10/2023	Yes	No