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Using umbilical cord stem cells to treat severe Chronic Obstructive Pulmonary Disease (COPD)

Submission date
25/04/2026

Recruitment status
No longer recruiting

Registration date
29/04/2026

Overall study status
Completed

Last Edited
29/04/2026

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 severe, long-term lung condition that makes it difficult to breathe. Patients with severe COPD often experience sudden, dangerous worsening of their symptoms called "flare-ups" (or acute exacerbations), which are driven by chronic inflammation throughout the body. Current standard treatments, like inhalers, help manage daily breathing symptoms but do not fix the underlying body-wide inflammation that triggers these flare-ups or stop the disease from getting worse. Stem cells taken from donated human umbilical cords—which are safely collected after healthy births—have a strong natural ability to calm down an overactive immune system and reduce inflammation. The aim of this study is to find out if giving patients a single dose of umbilical cord stem cells through a drip into a vein is safe, and whether it can successfully reduce the number of severe lung flare-ups they experience.

Who can participate?
Men aged between 40 and 80 years old who have been diagnosed with severe COPD and suffer from frequent lung flare-ups (defined as having at least two flare-ups, or at least one hospital admission due to a flare-up, in the past year). Patients who are currently smoking, have recently quit smoking (less than 6 months ago), or have other severe health issues like severe heart failure, active cancer, or other lung diseases (like asthma or tuberculosis) cannot participate.

What does the study involve?
This study compares two groups of patients over a 1-year period:
The Treatment Group: Participants in this group continue taking their standard daily COPD medications. In addition, they receive a single treatment of umbilical cord stem cells given as a slow drip into a vein (intravenous infusion). They stay in the clinic for 24 hours afterward to be safely monitored.
The Control Group: Participants in this group receive only their standard daily COPD medications, without the stem cell drip.

All patients are followed up for 12 months. During this time, they attend clinic visits at 1, 3, 7, and 12 months. At these visits, doctors record how many COPD flare-ups they have had, ask them to fill out questionnaires about their breathing symptoms and daily life, perform a 6-

minute walking test to check their fitness, and conduct standard lung breathing tests. Patients also give small blood samples so researchers can measure specific markers of inflammation in their body.

What are the possible benefits and risks of participating?
Possible Benefits: Patients receiving the stem cell treatment may experience a significant reduction in how often they get severe breathing flare-ups. They may also notice improvements in their daily breathing symptoms and overall quality of life.

Possible Risks: The stem cell infusion is considered very safe and well-tolerated. In this study, there were no serious allergic reactions or severe side effects. Possible minor, temporary risks right after the drip include a slight increase in blood pressure or mild, temporary changes in routine blood test results (like minor increases in liver enzymes or white blood cells). All of these minor changes went back to normal on their own without needing extra medication.

Where is the study run from?
The study is run across three medical centers in Vietnam: Van Hanh General Hospital (Ho Chi Minh City), 103 Military Hospital (Hanoi), and the National Lung Hospital (Hanoi).

When is the study starting and how long is it expected to run for?
The study started in January 2017 and patient follow-ups were completed in March 2021.

Who is funding the study?
Ministry of Science and Technology, Vietnam.

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Intravenous umbilical cord stem cells reduce exacerbations in severe COPD phenotypes

Study objectives
Safety: To evaluate the safety and tolerability of a single intravenous infusion of allogeneic UC-MSCs (1.5×10^6 cells/kg) alongside standard care, measured by the incidence of infusion-related toxicities and long-term adverse events over a 12-month follow-up period.
Clinical Efficacy: To evaluate the clinical efficacy of the UC-MSC infusion, measured primarily by the annualized rate of acute COPD exacerbations compared to a control group receiving standard care alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/09/2017, Van Hanh General Hospital (B1-B3-B5, 781 Le Hong Phong, Hoa Hung, Ho Chi Minh City, -, Viet Nam; +84 28 3863 2553; benhvienvanhanh@gmail.com), ref: 084/2017/QĐ-NCKH

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Single

Purpose
Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease stage C and D

Interventions
Intervention Group: A single intravenous infusion of allogeneic umbilical cord-derived mesenchymal stem cells (UC-MSCs) at a targeted dose of 1.5×10^6 cells/kg of body weight, diluted in 250 mL of 0.9% normal saline and administered at a controlled continuous rate of 70 drops/minute. Given alongside standard care.

Control Group: Standard care alone (optimized pharmacological treatments, e.g., LAMAs and LABAs).

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Mesenchymal stem cells

Primary outcome(s)
1. Safety and Clinical Efficacy measured using The frequency of acute COPD exacerbations, evaluated via clinical assessment and patient medical records and calculated as an annualized rate at 12 months

Key secondary outcome(s))

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. Confirmed COPD diagnosis meeting all of the following criteria
1.1 Post-bronchodilator FEV1/FVC ratio < 0.70
1.2 Negative bronchodilator reversibility
1.3 Classification into high-risk clinical phenotypes defined as Global Initiative for Chronic Obstructive Lung Disease (GOLD) groups C and D, characterised by ≥ 2 exacerbations or ≥ 1 hospitalisation for an exacerbation in the previous year

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
40 years

Upper age limit
80 years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Current smoking or smoking cessation within 6 months prior to screening
2. An acute COPD exacerbation requiring hospitalisation within 4 weeks prior to enrolment
3. Severe cardiovascular comorbidities, including ejection fraction ≤ 40 percent, recent myocardial infarction, or severe arrhythmias
4. Concurrent pulmonary diseases, such as asthma, tuberculosis, or idiopathic pulmonary fibrosis
5. Active malignancies
6. Immunodeficiency
7. Use of systemic immunosuppressants within 8 weeks prior to enrolment or TNF inhibitors within 3 months prior to enrolment

Date of first enrolment
01/01/2017

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
Viet Nam

Sponsor information

Organisation
Ministry of Science and Technology, Viet Nam

Funder(s)

Funder type

Funder Name
Ministry of Science and Technology, Viet Nam

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data (IPD) that underlie the results reported in this article will be shared in accordance with the ICMJE guidelines.

IPD sharing plan summary
Available on request