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Stem cell transplantation for chronic obstructive pulmonary disease treatment

Submission date	Recruitment status	[_] Prospectively registered
06/07/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/02/2020	Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the third leading cause of death overall. The main mechanism of COPD related to inflammation and its magnification in the lung and whole body. The current treatments including oxygen therapy, medications and physical therapy have limitations, especially in end-stage COPD.
Transplantation of mesenchymal stem cells (MSCs) maybe is an effective approach to treat COPD due to their immunomodulation property.
In this study, we aimed to evaluate the safety and efficacy of umbilical cord derived expanded mesenchymal stem cells transplantation in COPD treatment

Who can participate?
Stage C and D COPD patients

What does the study involve?
All participants were intravenously infused with qualified umbilical cord-derived stem cell with a dose of 1.5 million cells per kg and followed up for 6 months

What are the possible benefits and risks of participating?
Participants can receive the new method for treating COPD which is proved the safety and effectiveness in vitro and in vivo. The new method might help patients to control the disease and improve their quality of life.
Participants might have some side effects during the stem cell-based treatment. They are high fever, dyspnea, arrhythmias, creatinine increase, headache, sleep disorder. However, such symptoms are transient and relieve without any specific intervention

Where is the study run from?
1. Van Hanh General Hospital, Viet Nam
2. Vietnam Military Academy 103, Viet Nam

When is the study starting and how long is it expected to run for?
December 2019 to December 2019

Who is funding the study?
The Ministry of Science and Technology, Viet Nam

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
082/2017/QD-NCKH

Study information

Scientific Title
Umbilical cord-derived mesenchymal stem cell transplantation for chronic obstructive pulmonary disease treatment: a phase II clinical trial

Acronym
UCMSC-COPD

Study objectives
Umbilical cord-derived mesenchymal stem cells strongly display immune modulation potential compared to other kinds of mesenchymal stem cells that were isolated from other sources. Recent studies showed that adipose tissues and bone marrow-derived mesenchymal stem cell allogenic transplantation is safe and gives positive effects on the chronic obstructive pulmonary disease (COPD). However, there are not any clinical trials to evaluate the safety and efficacy of umbilical cord-derived mesenchymal stem cell transplantation for COPD treatment.

This study aimed to evaluate the safety and efficacy of allogeneic umbilical cord-derived mesenchymal stem cell transplantation for COPD patients.

We hypothesize that allogenic umbilical cord-derived mesenchymal stem cell transplantation is the promising method to treat COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2017, the Van Hanh General Hospital Ethical Committee (781/B1-B3-B5 Hm 781 Lê Hng Phong, Ward 12, District 10, Ho Chi Minh city, Viet Nam; Nghiencuukhoahoc@benhvienvanhanh.com; +84 2838632553), ref: 082/2017/QD-NCKH.

Study design
Interventional non-randomised parallel assignment single masking (participant)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (CODD) stage III and IV

Interventions
Patients were infused with 1-2 million cells of allogeneic in vitro expanded mesenchymal stem cells derived from umbilical cord tissues per kg body weight.

The umbilical cord was collected from the donor with consent forms. The mesenchymal stem cells from umbilical cord tissue were isolated and expanded in vitro using the UC-SCI technology (from Stem Cell Institute, VNUHCM University of Science, HCMC, Viet Nam). The umbilical cord-derived mesenchymal stem cell manufacturing procedure is compliant with good manufacturing practices (GMP).

All patients were followed-up for 24 at the hospital after transfusion; then followed-up up to 6 months

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Off-the-shelf human allogenic umbilical cord-derived mesenchymal stem cells

Primary outcome(s)
Improvement in pulmonary function determined by the incidence, frequency and/or severity of adverse events over 6 months after treatment compared to the same before treatment using patient notes

Key secondary outcome(s))
1. Respiratory function was measured by medical test to determine a change in FEV1 during 6 months of follow-up of stem cell transplantation
2. Exercise capability was measured by medical test to determine a change in 6-minute walking test during 6 months of follow-up after stem cell treatment
3. The degree of dyspnea was assessed by questionnaires to determine the mMRC and CAT scales before and 1month, 3 months, 6 months after stem cell treatment
4. The improvement of inflammatory response was measured by medical test to determine CRP concentration in the body before and 1month, 3 months, 6 months after stem cell treatment

Completion date
05/05/2019

Eligibility

Key inclusion criteria
1. Diagnosed with COPD stage C and D in accordance with GOLD 2016
2. Aged between 40 and 80 years old
3. Understand and agree to the written consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
Male

Total final enrolment
20

Key exclusion criteria
1. Current smoker or smoking cessation with the time of cessation less than 6 months;
2. Asthma or clinically relevant lung diseases other than COPD (lung tuberculosis, restrictive lung disease, idiopathic pulmonary fibrosis, lung cancer)
3. Active infection requiring antibiotic therapy
4. Active Mycobacterium infection
5. Clinically relevant not associated with COPD during screening: Left ventricle ejection fraction lower than 40%, valvular heart disease, cardiomyopathy disease, arrhythmia, congenital heart disease, kidney failure with Creatinine index > 2.0 mg/dl, liver disease with AST, ALT or bilirubin 2 times more than upper limit of normal range, haematological disorder or cancer
6. Using TNF inhibitor within 3 months prior to the screening visit
7. Using an immunosuppressive medicine 8 weeks prior to the screening visit
8. Active malignancy or history of cancer without recurrence within 5 years prior to the screening visit
9. Taking part in other clinical trials with any medicine or medical device
10. Unable to perform all of the assessments required for the study.

Date of first enrolment
05/05/2018

Date of final enrolment
05/05/2019

Locations

Countries of recruitment
Viet Nam

Study participating centre
Van Hanh General Hospital
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Sponsor information

Organisation
Stem Cell Institute, VNUHCM University of Science, Ho Chi Minh city, Viet Nam

ROR
https://ror.org/00waaqh38

Funder(s)

Funder type
Research organisation

Funder Name
Stem Cell Institute (VNUHCM University of Science, Viet Nam)

Funder Name
Van Hanh General Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/02/2020	17/02/2020	Yes	No