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Effect of high-flow nasal cannula on functional exercise capacity in hospitalized adult lung transplant candidates: a modified cross-over study

Submission date
17/01/2025

Recruitment status
No longer recruiting

Registration date
20/01/2025

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This study aims to find out whether a high-flow nasal cannula can increase the meters walked in the 6-minute walk test (6MWT) compared to conventional oxygen therapy, and also whether it improves exercise tolerance and reduces dyspnea (shortness of breath) and recovery times in patients with chronic respiratory disease.

Who can participate?
Hospitalized adults (18 years of age or older) with pulmonary hypertension or pulmonary fibrosis who are candidates for lung transplantation

What does the study involve?
Participants will perform four 6MWTs: one with supplemental oxygen delivered by reservoir mask and three with high-flow nasal cannula at 40, 50 or 60 LPM. The researchers will evaluate 6MWT performance and physiological response to exercise.

What are the possible benefits and risks of participating?
If a high-flow nasal cannula improves performance and provides an adequate physiological response in the 6MWT, it would support using this device for better results in pulmonary rehabilitation programs in hospitalized patients. However, during the performance of the 6MWT, some adverse events may occur, such as falls, syncope (fainting), or increased oxygen requirements or respiratory support.

Where is the study run from?
Instituto Nacional del Tórax (Chile)

When is the study starting and how long is it expected to run for?
June 2024 to December 2026

Who is funding the study?
Instituto Nacional del Tórax (Chile)

Who is the main contact?
Ruvistay Gutierrez-Arias, rgutierrez@torax.cl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
CECSSMOriente060824-1

Study information

Scientific Title
Effect of high-flow nasal cannula on the 6-minute walk test in hospitalized patients with pulmonary hypertension or pulmonary fibrosis who are candidates for lung transplantation: a modified cross-over study

Acronym
HELCOS

Study objectives
It is hypothesised that using high-flow nasal cannula with flow levels of 40, 50, and 60 LPM increases the metres walked in the 6-minute walk test (6MWT) compared to conventional oxygen therapy. In addition, it improves exercise tolerance and reduces dyspnoea levels and recovery times in hospitalised patients with pulmonary hypertension or pulmonary fibrosis who are candidates for lung transplantation. Performance on the 6MWT and physiological response to exercise should improve the higher the flows used.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 06/08/2024, Scientific Ethics Committee of the Servicio de Salud Metropolitano Oriente (Santiago, Chile). (Avenida Salvador #364, Santiago, 7500000, Chile; +56 (0)9 9832 8739, +56 (0)9 8156 6931; comite@cec-ssmoriente-adultos.cl), ref: CECSSMOriente060824-1

Primary study design
Interventional

Study design
Modified randomized cross-over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hospitalised adults with pulmonary hypertension or pulmonary fibrosis who are candidates for lung transplantation

Interventions
The study participants will perform four 6MWTs: one with supplemental oxygen delivered via reservoir mask and three with high-flow nasal cannula at 40, 50 or 60 LPM. An inspired fraction of oxygen will be delivered during each test to maintain oxygen saturation above 90-92%. The temperature will be adjusted to 31-37°C in the high-flow nasal cannula according to patient-reported comfort. The order of performance of the four 6MWTs will be randomized for each patient. The tests will be performed at an interval of 3 days. On the day the tests are conducted there will be no physical training sessions before the evaluations. In addition, during rest days, patients will undergo low-intensity physical rehabilitation.

A computer program will generate the randomization sequence for the order in which the 6MWTs are performed (randomized.org). The researcher who recruits the participants and performs the evaluations will not learn about this assignment until the first test is administered.

Intervention Type
Other

Primary outcome(s)
Functional capacity to perform exercise: the distance walked in each 6MWT will be measured. nt. The four tests will be performed at an interval of 3 days.

Key secondary outcome(s)
1. Physiological response to physical exertion:
1.1. Respiratory rate will be monitored with a multiparameter transport monitor every minute during all 6MWT and at 1, 3, 6, and 10 minutes after the end of the tests.
1.2. Heart rate will be monitored with a multiparameter transport monitor every minute during all 6MWT and at 1, 3, 6, and 10 minutes after the end of the tests.
1.3. Peripheral oxygen saturation will be monitored with a multiparameter transport monitor every minute during all 6MWT and at 1, 3, 6, and 10 minutes after the end of the tests.
1.4. Lower extremity fatigue will be assessed with a simple numerical scale (NRS) from 0 to 10 every minute during all 6MWT and at 1, 3, 6, and 10 minutes after the end of the tests.

1.5. Dyspnea will be assessed with the modified Borg scale every minute during all 6MWT and at 1, 3, 6, and 10 minutes after the end of the tests.
2. Stops during the 6MWT: stops during each test will be counted, and the patient will be asked for the reasons.
3. Walking time: Patients' total walking time will be determined. This time will be calculated by subtracting the time spent stopped from the total time of the 6MWT (6 minutes).
4. Time to return to calm: when vital signs, lower extremity fatigue and dyspnea return to baseline values will be determined. This will be assessed up to minute 10 of each 6MWT.
5. Adverse events: adverse events directly associated with the performance of the 6MWT will be recorded. Falls, syncope, and increases in oxygen requirements and respiratory support during the same day of the four 6MWTs will be considered. Deaths and the need for invasive mechanical ventilation or extracorporeal circulatory support will also be considered.

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Adult persons (18 years of age or older)
2. Persons with a group I or III pulmonary hypertension diagnosis as defined by the World Health Organization (WHO). Diagnosis can be made by echocardiogram or cardiac catheterization
3. Persons with a diagnosis of pulmonary fibrosis. Diagnosis may be made by computed tomography (CT) or lung biopsy
4. Persons under study to enter the lung transplant list or enlisted at the time of study execution
5. Stable medical condition, defined as no change in medication in the last 14 days before assessment
6. Indication from the treating medical team to perform out-of-bed motor rehabilitation
7. Having previously undergone a 6MWT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Key exclusion criteria

1. Persons with exacerbation of pathology due to infectious, inflammatory process or disease progression
2. Persons with a resting heart rate greater than 120 beats per minute
3. Persons with unstable hemodynamics (MAP <60 mmHg or >100 mmHg)
4. Persons connected to a high-flow nasal cannula with flows equal to or greater than 40 LPM at rest
5. Persons in need of continuous or intermittent connection to noninvasive mechanical ventilation
6. Persons with neuromusculoskeletal alterations or need for technical aids that limit independent walking
7. Persons who do not understand the instructions necessary to perform the 6MWT
8. Persons who do not sign the informed consent

Date of first enrolment
15/08/2024

Date of final enrolment
15/08/2026

Locations

Countries of recruitment
Chile

Study participating centre
Instituto Nacional del Tórax
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Sponsor information

Organisation
Instituto Nacional del Tórax

ROR
https://ror.org/00t0z3q71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto Nacional del Tórax

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ruvistay Gutierrez-Arias (rgutierrez@torax.cl).
The type of data that will be shared: anonymized Excel file.
Dates of availability: 5 years after the study is published.
Whether consent from participants was required and obtained: yes. All study participants will sign a consent form.
Comments on data anonymization: the data will be stored anonymously in an Excel spreadsheet.
Any ethical or legal restrictions: the data may be presented with the authorization of the study's corresponding author.
Any additional comments: the data may be used for meta-analysis of individual patient data with the prior authorization of the study's corresponding author.

IPD sharing plan summary
Available on request