Effects of High-Flow Nasal Cannula on Exercise Outcomes in Lung Transplant Candidates: A Pilot Study

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RESEARCH PROTOCOL

"Effects of High-Flow Nasal Cannula on Exercise Outcomes in Lung Transplant Candidates: A Pilot Study"

Isabela Belarmino Oliveira de Castro

Informed Consent Form

Patients aged ≥ 18 years

Introduction

You have been invited to voluntarily participate in the study: **"Comparison Between the Effects of High-Flow Nasal Cannula and Conventional Oxygen Therapy on Exercise Outcomes in Patients with Ventilatory Limitation on the Lung Transplant Waiting List: A Pilot Study."** If you decide to participate, you will need to be informed of the potential risks and benefits and confirm your participation through the Informed Consent Form.

This document provides information about the study you are considering joining. If you have any questions, please feel free to contact the physician responsible for the study or any professional involved in the research who can clarify your doubts.

Participation in this research is voluntary, and you may refuse or withdraw at any time without any impact on your treatment. The aim of this research is to compare the effects of high-flow nasal cannula and Venturi mask or non-rebreather mask during physical treadmill tests, as already conducted in the pulmonary transplant rehabilitation clinic.

Procedures Involved in This Protocol

Your medical history will be collected, a physical examination will be performed, followed by ventilatory measurements. This evaluation will be identical to the one you underwent during the initial assessment of rehabilitation

and after 36 training sessions. Three tests (each test will be duplicated) will be conducted on a treadmill over 6 days. The first test will be a six-minute walk test, setting the walking speed, followed by an incremental lower limb (LL) test with ramp increments, and finally, an endurance LL test, which may last up to 60 minutes. As each test will be duplicated, the type of oxygen therapy for each test day will be randomized. All tests will be stopped at the limit of maximal effort, using the modified Borg Scale of Perceived Exertion, considering a score greater than 7, an increase in heart rate exceeding the submaximal limit determined by your age, and symptoms of dizziness and visual darkening. Before and after some tests, ventilatory measurements will be taken. On the days when the incremental test is performed, arterial and venous blood gas samples will be collected before and after the test, totaling 8 arterial and 8 venous samples. The purpose of these blood tests is to detect changes in CO2 (carbon dioxide) levels in arterial and venous blood. You will have access to your test results at any time after they are issued; no one except the involved researchers will know the results. A trained and academically qualified person (nurse) will collect approximately 5 ml of blood. The blood samples will be sent for processing at the central laboratory immediately after collection.

Risks and Inconveniences

During the arterial blood gas collection procedure, the needle insertion may cause pain. Although rare, bleeding at the puncture site and formation of a bruise (hematoma) may occur. To minimize bleeding, it is important to apply pressure to the site for 3 minutes after blood collection. You may experience signs of exhaustive exertion; however, the tests will be limited and stopped at your maximal effort limit, as practiced during rehabilitation training.

Benefits of the Treatment

The high-flow nasal cannula has been used during training with positive responses and acceptance. However, there are still questions about its effects on training outcomes compared to other oxygen therapies. Therefore,

developing a protocol using this device in cardiopulmonary rehabilitation is relevant, as it will allow for assessing its feasibility during aerobic performance.

Alternative(s) to Participation in the Study

You have the right to ask questions or refuse to participate in this study, as well as the right to withdraw from participation at any time. Furthermore, if you agree to participate, we assure you that you will receive clarification of any doubts, the freedom to withdraw your consent, and to stop participating in the study at any time without any harm to you.

Participant Rights

Your participation is voluntary, and you may withdraw your consent or discontinue your participation at any time, if you wish, without any penalties or adverse effects.

There will be no costs to you resulting from this study, nor will you receive any compensation for your participation. By signing this consent form, you do not waive any legal rights.

Participant Duties

As you have rights, there are also duties you must fulfill if you choose to participate in this research. The main obligations are:

- Attend all scheduled evaluation days as planned.
- Follow the study protocol, performing the requested procedures as directed by the study team.
- Inform the researcher of any changes in your health status and any medications used during the period.
- Report any unexpected effects to the researcher as soon as possible.

Health Damages

If an injury or any health damage occurs as a proven result of your participation in this research, comprehensive assistance will be available at no cost to you.

Confidentiality

The study team and healthcare team will have access to your data; however, your anonymity is guaranteed, and any scientific publications resulting from this study will not identify you as a participant under any circumstances. The data obtained will be treated with strict confidentiality.

Your data may also be shared with the following groups associated with this research or involved in research review: other members of the Principal Investigator's research team, the Clinical Research Center team, the Research Ethics Committee, the Legal Department, and government representatives or federal agencies, when required by law. If new information arises that may be important to your decision to continue in the study, you or your legal representative will be informed as soon as the data becomes available. This study has been approved by the Research Ethics Committee (CEP), which is responsible for approving studies involving human subjects.

For any general questions and/or questions related to participant rights (right to clear information, related costs, medical and hospital follow-up in case of damage resulting from participation in the research, data confidentiality, access to results), please contact the Research Ethics Committee at phone 11 2151 3729 / FAX 11 2151-0273 / email cep@einstein.br.

For any questions related to the study, please feel free to contact the physiotherapists responsible for conducting the study: Isabela Belarmino Oliveira de Castro, cell (12) 98116 4164; Elaine Cristina Pereira, cell (11) 97162 5757; Thaís Melatto Loschi, cell (11) 96722 7535. Complaints, praise, and suggestions should be directed to the Customer Service System (SAC) via phone (11) 2151-0222 or through the "contact us" form available on the clinical research page or in person.

Consent Signatures

I have been informed of all the details related to the study to which I will be subjected. I will receive a signed and dated copy of this Informed Consent Form. I also understand that the collected material will be used exclusively to answer the research questions and to ensure my safety. After the tests, my blood will be discarded.

Full Name of Research Participant Date

Signature

Full and Legible Name of the Principal Investigator Date

Signature