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INFORMATION AND CONSENT FORM

Research Study Title:	Phase I Safety and Feasibility Pilot Study of Same-Day Discharge after Video-Assisted Thoracoscopic Surgery (VATS) Anatomical Lung or Wedge Resection
Protocol Number:	2021-7318
Researcher responsible for the research study:	Jonathan D. Spicer[1], MD PhD
Co-Investigator(s):	Caroline Huynh[1], MD Severin Schmid[1], MD Lorenzo Ferri[1], MD PhD Christian Sirois[1], MD Jonathan Cools-Lartigue[1], MD PhD Sara Najmeh[1], MD MSc Florin Costescu[2], MD Gabriele Baldini[2], MD MSc David Bracco[2], MD Andrew Owen[2], MD Danielle Shafiepour[2], MD Alexander Amir[2], MD Francesco Donatelli[2], MD Juan-Francisco Asenjo[2], MD

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INTRODUCTION

We are inviting you to take part in this research study because you are about to undergo a minimally-invasive lung surgery called video-assisted thoracoscopic surgery (VATS).

However, before you accept to take part in this study and sign this information and consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the "study doctor") or to other members of the research team, and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

Enhanced recovery after surgery (ERAS) is a program that has been implemented in many surgical specialties. The ERAS program includes counselling before surgery, nutrition optimization, pain control through multiple approaches, and early ambulation (moving as soon as possible after the surgery). ERAS is a model that was introduced in the 1990s, and enhanced recovery pathways (ERP) have been implanted in our institutions for approximately 10 years, including for your type of surgery, the video-assisted thoracoscopic surgery (VATS).

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to evaluate the safety and feasibility of same-day discharge in selected participants undergoing minimally-invasive lung surgery and who receive an ERP. Moreover, we aim to assess the impact on complications and recovery using this specific ERP for same-day discharge.

For this research study, we will recruit 20 participants, men and women, aged 18 and above.

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at the McGill University Health Centre's academic Upper Gastrointestinal and Thoracic Surgery division located at the Montreal General Hospital (MGH).

1. Duration and number of visits

Your participation in this research project will last between 2-3 months. This includes clinical visits (1 pre-operative visit, 1 surgical and post-surgical in-hospital visit, and 1 follow-up visit) during which research procedures will also occur, and will include additional research visits (3 phone follow-ups, and 1 in-person follow-up visit).

2. Overview of study participation

If you agree to participate in this research study, the surgery will be done in the same way as if you decide to not participate in this study.

If you agree to participate in this research study, you will be asked to follow the ERP that includes counselling before surgery, nutrition optimization, pain control through multiple approaches, and early ambulation (moving as soon as possible after the surgery), and to complete two questionnaires at different moment in the study (described below).

If you meet certain criteria, you will leave the hospital on the same day as the day of surgery. Usually, people who have the same surgery as yours stay in the hospital for 2 days. Leaving the hospital the same day is done only for the research. You are advised to have an experienced caregiver capable of responding to your needs upon discharge (leaving the hospital).

After the surgery, a tube will be inserted into your chest and connected to a small portable draining device, which is done for anyone receiving the same surgery as yours. However, as part of the research, you will also be discharged with this tube in place and the device. The tube will be removed as soon as no air or large amounts of bloody fluid are being drained anymore. This can be as early as on the second postoperative day.

3. Tests and procedures

During your participation in this research study, the study doctor or a member of the research team will conduct the following tests and procedures:

DESCRIPTION OF RESEARCH PROCEDURES	
Procedure	**Description**
Review of your medical chart	The research team will review your medical chart to collect data necessary for the research, such as your age, your sex, your past medical and surgery history, your lung function test results, details about your type of cancer, and details about your surgery including any complication.
Enhanced recovery pathway (ERP)	This includes counselling before surgery, nutrition optimization, pain control through multiple approaches, and early ambulation (moving as soon as possible after the surgery). The anesthesia plan put in place in this research was created by the Department of Anesthesiology as a consensus, and uses different elements already done as part of standard of care, but were specifically selected together for an optimized ERP for same-day discharge. These optimized measures aim to help early discharge home after surgery.
Quality of life and symptom questionnaires	You will be asked to answer 2 short questionnaires, the Functional Assessment of Cancer Therapy - Lung (FACT-L) and the Edmonton Symptom Assessment System (ESAS), which will assess your quality of life and symptoms. You will be asked to complete these questionnaires, which will take

DESCRIPTION OF RESEARCH PROCEDURES	
Procedure	**Description**
	approximately 5 minutes, at the time of consenting to the study, on the day of your surgery, after chest tube removal and on day 30 after your surgery.
Chest tube insertion	As part of your surgery, a chest tube drain will be inserted in one of the incisions to allow for air between the lung and the chest wall to be suctioned and permit the lung to re-expand. This is performed for anyone receiving the same surgery as yours. However, as part of the research, you will also be discharged with this tube in place and the device attached to it. The chest tube drain is connected to a small portable drainage system reservoir called the Mini Atrium 500 which allows for air and fluid suction and emptying. The chest tube should always be secured to your skin with a wide piece of tape to prevent accidental movement of the tube. Avoid sudden movements that can result in dislodgement of the tube and prevent any pulling on the tube. The chest tube site needs to remain clean; the nursing staff will instruct you on the proper way to ensure cleanliness of the site as well as how to take care of the tube. Ensure that the connections between the portable drainage system and the tube are well secured and do not come apart. <u>If the tube accidentally pulls out, notify the clinical team right away.</u>
Follow-up visits	Your surgeon and their team will see you call you daily until chest tube drain removal or post-operative day 5. You will be seen in follow-up on post-operative day 2, and on day 5 if your chest tube was not removed on day 2.

The schedule of procedures for each visit is listed below:

SCHEDULE OF STUDY PROCEDURES								
Procedure	**Prior to surgery (Day of consent)**	**Visit 1 (Surgery)**	**Visit 2 (After your surgery)**	**Visit 3 (After your surgery, Day 1)**	**Visit 4 (After your surgery, Day 2)**	**Visit 5 (After your surgery, Day 3-4)**	**Visit 6 (After your surgery, Day 5)**	**Visit 7 (After your surgery, Day 30)**
Quality of life questionnaires	X	X			+		+	X
Follow-up visits			X	*	X	*	#	*
Chest tube removal					+		+	

Legend:

+: This procedure occurs on one of these visits.

*: These visits are phone follow-ups.
#: This visit may occur if needed.

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

You may or may not personally benefit from your participation in this research project. However, we hope that the study results will contribute to the advancement of scientific knowledge in the study field and help us find better treatments for patients.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

The study intervention, the ERP for same-day discharge, is experimental and therefore we may not know all the discomforts, side effects and other possible risks associated with it.

Risks associated with the study intervention

These consist of anything resulting from the absence of immediate access to nurses and/or doctors as would be provided in a hospital, given that the standard discharge target for people undergoing the same surgery as you is 2 days.

The risk of an early discharge would be that the same surgical complications as with any other VATS surgery. If they were to go unrecognized, it could lead to a higher severity of complication and require a re-visit with the treating doctor. Possible surgical complications can include:

- unrecognized bleeding
- retaining urine longer than usual (urinary retention)
- heart rhythm changes (arrhythmias)
- air between the lung and the chest wall (pneumothorax).

Your safety is the number one priority during this study. The study team does not expect any issues resulting from an early discharge home. Therefore, if you notice any issues, whatever they may be, during this research study, you must tell the study doctor immediately, regardless of whether you think these issues are related to the study intervention or not. Even once your participation in the study has ended, do not hesitate to contact the study doctor if you experience any problems that may be linked to the study intervention.

Risks related to the questionnaires

You may find upsetting or distressing to answer some questions. You can refuse to answer those questions and/or choose to stop participating in the study altogether at any time. You do not have to give any reason for refusing to answer a question or for stopping to participate. If you feel uncomfortable at any time, do not hesitate to tell the researcher(s). Our clinical nurse will evaluate your mental, physical, and emotional state to ensure a safe and comfortable questionnaire environment.

Risks related to the chest tube

Normally, the chest tube is removed on the second day after surgery before discharge, or at a follow-

up visit between 5 to 7 days after surgery if the patient goes home with it. To facilitate a same-day discharge, you will be going home with your chest tube. There are potential risks of taking care of your chest tube at home such as tube fall-out, difficult wound care or wound infection. In addition, you may find inconvenient to return to our clinic on the second day after surgery (and maybe on the fifth day after surgery, if necessary) to get your tube removed.

Other risks

A possible risk associated with this study is a breach of confidentiality or use of your personal information by a third party. To limit this risk, we will take the steps to protect your confidentiality described in the Confidentiality section, below.

The study doctor and members of his or her team will answer any questions that you may have regarding the risks, discomforts and side effects associated with this study. Also, at each visit, the study doctor and members of his or her team will ask you questions about any side effect you may have experienced.

OTHER POSSIBLE TREATMENTS

You do not have to take part in this study to receive medical care for your condition. We encourage you to discuss with the study doctor all available options.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor, or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, the information already collected for the study will be stored, analyzed and used to ensure the integrity of the study.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

CONFIDENTIALITY

During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from your medical chart, including your identity, concerning your past and present state of health, your lifestyle, and details about your cancer. Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.

All the information collected during the research project will remain strictly confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the study doctor.

To ensure your safety, a copy of this information and consent form, and information related to your surgery such as operative and pathological data will be placed in your medical chart. As a result, any person or company to whom you give access to your medical chart will have access to this information.

The study data will be stored for 7 years by the study doctor.

The data may be published or shared during scientific meetings; however, it will not be possible to identify you.

For auditing purposes, the research study files, which could include documents that may identify you, may be examined by a person mandated by the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

However, in order to protect the scientific integrity of the research project, accessing certain information before the project is ended may require that you be withdrawn from the study.

INCIDENTAL FINDINGS

Material incidental findings are findings made in the course of the study that may have significant impacts on your current or future wellbeing or that of your family members. A material incidental finding concerning you in the course of this research will be communicated to you and to a health professional of your choice.

FUNDING OF THE RESEARCH PROJECT

The study is not funded.

COMPENSATION
You will receive 50$ in financial compensation for participating in this research study, due to the inconvenience of returning to the clinic 2 days after your surgery for follow-up and chest tube removal. This compensation is provided by the Division of Thoracic Surgery Account.

SHOULD YOU SUFFER ANY HARM
Should you suffer harm of any kind following administration of any procedure related to the research study, you will receive the appropriate care and services required by your state of health.

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the study doctor, the sponsor or the institution, of their civil and professional responsibilities.

CONTACT INFORMATION
If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with the study doctor or with someone on the research team at the following number:

Dr. Jonathan Spicer at 514-934-1934 ext 43050.

For any question concerning your rights as a research participant taking part in this study, or if you have comments, or wish to file a complaint, you may communicate with:

Patient Ombudsman of the McGill University Health Centre at the following phone number: 514-934-1934 ext 48306.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH
The McGill University Health Centre Research Ethics Board reviewed this research and is responsible for the ongoing ethics oversight of the study.

Research Study Title: Phase I Safety and Feasibility Pilot Study of Same-Day Discharge after Video-Assisted Thoracoscopic Surgery (VATS) Anatomical or Wedge Lung Resection

SIGNATURES

Signature of the participant

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.

I authorize the research study team to have access to my medical record for the purposes of this study.

I authorize the doctor in charge of this research study to communicate with me directly to ask if I am interested in participating in other research:

Yes ☐
No ☐

I authorize the study doctor to inform my treating physician that I am taking part in this study:

Yes ☐ Name and contact information of treating physician: _____
No ☐
I do not have a treating physician/I am no longer being followed by my treating physician ☐

I understand that the study doctor will send my treating physician health information if it will be useful for my care.

Name of participant	Signature	Date

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent	Signature	Date

SIGNATURE OF WITNESS

☐ Yes ☐ No

A witness' signature is required in the following cases:

☐ Reading disability or inability to read – The witness (impartial) signing below attests to the fact that they read the Informed Consent Form, that the study was precisely explained to the participant, and that the participant seems to have understood it.

☐ Foreign language (participant does not understand the language in which the Informed Consent Form was written) – The signatory attests to acting as interpreter for the participant throughout the consent process.

☐ Inability to write (participant is capable of providing consent, but unable to write).

Name of the witness	Signature	Date