

PATIENT INFORMATION AND CONSENT FORM

Study Title

An Efficacy Study of Positron Emission Tomography with [F-18] Fluorodeoxyglucose in Oncology Patients.

Principal Investigator: Dr. David Webster
1-705-675-4714

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Background

You are being asked to participate in a research study of the investigational radiopharmaceutical (a radioactive drug) [F-18] Fluorodeoxyglucose (FDG) with positron emission tomography (PET) in the diagnosis of a primary tumor and the management of care in cancer patients. ¹⁸F-FDG PET is a nuclear medicine imaging procedure which is commonly referred to as ¹⁸F-FDG PET.

Who can answer my questions?

You may contact Care Imaging at any time and ask any question you have about this study. The telephone number is (905) 712-9500. You may also wish to discuss with your physician about participating in this study.

How many patients will take part in the study?

This study is expected to enroll approximately 1800 patients.

How long will I be in the study?

You will be in the study for one 3-hour period (single visit).

Why is this study being done?

This study is being done to see whether ¹⁸F-FDG PET scan gives the same results as standard methods (e.g. biopsy) in assessing your condition to measure the change that ¹⁸F-FDG PET scan may have on your cancer treatment.

Before your PET scan, ¹⁸F-FDG is injected into your body, and concentrates in areas of diseased tissue. A PET camera is then used to take picture of the distribution of FDG in your body. A qualified nuclear medicine physician will interpret the ¹⁸F-FDG PET picture. ¹⁸F-FDG PET is a nuclear medicine procedure, similar to SPECT (Single Photon

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Emission Computed Tomography), which is commonly available in Canada. However, FDG PET may be more accurate in assessing certain cancers such as yours, as well as heart disease and certain brain diseases.

What will happen in the study?

The referring physician will conduct conventional diagnosing methods (CDM) and patient history prior to the ^{18}F -FDG PET scan. Then the principal investigator of this study will determine if you are eligible to participate in this study. If eligible, you will receive a copy of this informed consent form (ICF) at least 4 days before your appointment. The informed consent form (ICF) must be signed at the clinical site just prior to the scan.

You will arrive at one of the three clinical trial sites at a pre-arranged scheduled ^{18}F -FDG PET scan appointment.

You must have fasted for at least 6 hours before your scheduled ^{18}F -FDG PET scan appointment time. If you are a diabetic, you must fast (no eating or drinking beverages) at least - 4 hours before the ^{18}F -FDG PET scan. You may take medications as necessary, or water as desired.

A study monitor will explain the ICF to you upon arrival at the clinical trial site. The principal investigator or sub-investigator will be available by telephone to answer any questions you may have regarding this ICF.

Once the ICF has been signed, the following will be conducted:

- Blood sample taken to measure your sugar levels
- A urine pregnancy test will be performed on women of reproductive age
- Vital signs (i.e. blood pressure, heart rate, and temperature) will be taken prior to administration of the study drug.
- Your weight will be measured to calculate the dose for the ^{18}F -FDG

Once the tests are done and checked for eligibility to continue the study, you will be given a small amount of intravenous (IV) dose of ^{18}F -FDG PET solution based on your current weight.

You will then be instructed to rest in a quiet darkened room for 45 to 60 minutes prior to the PET scan. After resting, you will be instructed to empty out your bladder prior to the PET scan. Pictures of your body will be taken using a PET scanner, which will approximately take one and half hours. Once the study is complete, your vital signs (i.e. blood pressure, heart rate, and temperature) will be checked prior to leaving the trial site.

Results of your scan will be sent to your referring physician. The entire procedure should take about 3 hours of your time.

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What are the possible risks to me from the study?

In this study, a blood sample will be collected to measure your blood sugar levels in which case you may experience pain, bruising or discomfort at the injection site. You may also experience pain and tenderness, bruising or a skin reaction at the injection site when given a one time ¹⁸F-FDG IV injection. There are no known risks associated for ¹⁸F-FDG PET solution.

Radiation Risk:

The PET scan involves the use of radiation. The radiation dose is very low and the risk to you from radiation exposure is too small to be measured. In our day to day activities, we are exposed to various types of naturally and artificially occurring radiation. There is insufficient information to determine the risk to the unborn fetus or child.

You may experience claustrophobia from being inside the PET scan ringer or experience mild discomfort from lying on the PET scanner table. A sedative such as Diazepam or lorazepam may be prescribed to you if you are unable to relax, lie still, or for those who experience claustrophobia. There can be side effects from diazepam or lorazepam. The more common side effects are drowsiness, dizziness, dry mouth, diarrhea, upset stomach, blurred vision.

As with any research study, there is a risk of side effects. You should discuss this with your physician. Not all patients will experience side effects. A study monitor or nuclear medical technician will monitor you closely to see if you experience any side effects. Most side effects go away in a few hours, but in some cases side effects can be serious or life threatening.

If you experience any unusual signs or symptoms, please report them to the study monitor or the principal study physician.

Are there benefits to taking part in the study?

The PET Scan may allow your physician to better diagnose your medical condition, evaluate your response to the medical treatment, or change the course of your current cancer medical treatment to further optimize your medical treatment. However, it is possible you may not benefit from your participation in this study.

What other choices do I have if I don't participate in the study?

PET scanning is currently not provided as a clinical service by Ontario Health Insurance Program (OHIP). If you choose not to participate, your usual course of medical care will continue. You may drop out of the study at any time.

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What are the costs of tests and procedures?

Your ability to pay for the ^{18}F -FDG PET scan will not influence your eligibility for participation in this study. If you demonstrate a financial need, you will be referred to the appropriate financial aid source and may qualify for financial aid.

Applicants must meet the following criteria to be eligible for financial assistance:

1. Be a Canadian citizen or landed immigrant and be living in Canada,
2. Demonstrate financial need,
3. Have a demonstrated requirement for a PET scan as defined by the referring physician who is enrolled in the applicable Clinical Trial
4. We require at least two weeks notice, to allow us time to confirm scanning times and financial need.

Applicants will be assessed on individual bases. For further information, or to apply for financial assistance, please contact Care Imaging at 905-712-9500.

The total cost of the study will be \$2358 dollars (CAD funds) per scan payable at time of ^{18}F -FDG PET scan. This price covers the cost (including shipping and handling) of the radiopharmaceutical FDG and costs associated with the PET Scanner.

If you are unable to complete the scan within two scheduled appointments due to high blood sugar levels (i.e. uncontrolled hyperglycemia) or claustrophobia, no future appointments will be made as part of this study.

Will I receive any compensation for my participation in the study?

Medical treatment would be provided in the case of an injury as a result of participating in this study. CI Pharma Inc. will provide, or arrange for medical treatment. Such medical treatment will be covered by CI Pharma Inc. if not covered by your provincial health insurance plan or private medical insurance (if any).

What are my rights if I take part in the study?

Taking part in the study is voluntary and your decision. You do not have to take part in this study, but if you do, you may drop out of the study at any time. This will not affect the standard medical treatment you receive now or in the future. By signing this form, you are not giving up your legal rights, not releasing the study doctor or sponsors from their legal and professional obligations.

How will my privacy be protected?

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Data taken from this study may be published. However your name and other identifying information will be kept confidential and will not be made publicly available. Representatives from Health Canada or **the Institutional Review Board (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants)** may review your personal and medical records **if** requested.

All scanning data will be maintained at CI Pharma Inc. for a period of least twenty-five years, and governed by the privacy policies of CI Pharma Inc. Your medical records related to this study will also be given to your Oncologist.

FURTHER INFORMATION

If you experience any unusual signs or symptoms or side effects, or if you experience a research-related injury and need medical treatment, please immediately contact the study physician or the principal physician investigator responsible for this study, Dr. David L. Webster at (705) 675-4799 or go to the nearest hospital emergency department.

- The ethical aspects of this protocol have been reviewed by Institutional Review Board of IRB Services, an independent Canadian research ethics board. CI Pharma Inc. may stop you from participating in the study at any time if it is in your best interest, if you do not follow the protocol rules, or if the study is stopped. If you have any questions about your rights as a study participant, you may contact your family doctor, lawyer, or write to the research ethics board at: The Secretary, IRB Services, 14845-6 Yonge Street #328, Aurora, Ont. L4G 6H8. If you have questions about your rights as a research subject you may also call IRB Services' bilingual Representative, Prof. Albert Jordan at 450-532-4130.

My signature below means I have read the patient information and consent form, my questions have been answered to my satisfaction, and that I agree to participate in this study. A copy of this signed patient information and consent form will be given to me. I understand that even though I have read and signed this consent form, I can withdraw from the study at any time if I so do wish. I will not donate blood while I am in the study and for at least 30 days after.

Patient's Name (Please Print)

Patient's Signature

Date

Person Conducting Informed
Consent Discussion
(Please Print)

Signature of Person Conducting
Informed Consent Discussion

Date

Patient Initials _____

Investigator's Name (Please Print)

Investigator's Signature

Date

Patient Initials _____