

PHYSICIAN 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

Site Address: CI Pharma Inc.
246 Matheson Blvd. E.
Mississauga, ON L4Z 1X1

Background

You are being asked to participate in this study because you have patients who have, or are suspected of having one of the following forms of cancer: lung, breast, colorectal, malignant melanoma, or lymphoma. This study is being done to determine the sensitivity and specificity of ^{18}F -FDG PET in the diagnosis of the primary tumor and to measure the change it might have on your patient's therapeutic management.

^{18}F -FDG, is a glucose analogue that is applied clinically to detect and stage a variety of cancers. The use of glucose metabolism to differentiate malignant tumors is based on the biology of neoplastic degeneration, which has been shown to exhibit high rates of glucose consumption in malignant tissue. Like glucose, ^{18}F -FDG is a substance for facilitated transport and is phosphorylated by hexokinase in tumor cells. However, FDG-6- PO_4 is not catabolized and remains trapped in tumor cells. Therefore, the relative distribution of FDG-6- PO_4 can serve as a marker of glucose metabolism in the organ systems of the body, which can then be imaged with a PET scanner.

What are the benefits and risks to your patients?

The results of this study may help identify regions of your patient's body that have been involved with tumors. This information may help you make additional plans for your patient's care. The data collected from this study will also be used to support increasing accessibility to PET for your patients.

This is a nuclear medicine procedure; therefore, your patients will be exposed to ionizing radiation from the intravenously injected ^{18}F -FDG. Millions of ^{18}F -FDG PET scans have been performed and there have been no reported adverse effects from the medical literature. A PET scanner is approximately the same size as a CT scanner. The scan lasts approximately 45 – 60 minutes, and some patients may experience claustrophobia.

What are the costs of tests and procedures?

For your patient(s), the cost of participating in this study is \$2,358 payable at the time of the scan. If a patient is unable to pay for the ^{18}F -FDG PET scan and capable of

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demonstrating financial need there is a limited fund available. Please call CI Pharma Inc. to inquire.

Who can answer my questions?

You may contact CI Pharma Inc. at any time and ask questions. The telephone number is (905) 712-9500.

What about confidentiality?

Data in this study may be published. However, your name and other identifying information will not be published. Your patient's name and other identifying information will not be published.

What is my involvement in the study?

Prior to the study, you will be expected to complete and provide the information requested in the Referring Physician's Screening Form. Once the study is completed, you will be expected to provide follow-up data as outlined in the Referring Physician's Follow Up Form.

How soon should I expect to receive the results of the ¹⁸F-FDG PET?

The results of the study will be sent to your office approximately 72 hours after the scheduled ¹⁸F-FDG PET scan.

Are there any special instructions for my patient(s)?

You should advise your patient to fast for 6 hours prior to their scheduled ¹⁸F-FDG PET scan appointment. If the patient is diabetic they are required to fast for a minimum of 4 hours prior to their scheduled appointment.

I have had an opportunity to have my questions answered. I have been given a copy of the Referral Physician's Screening Form and Referral Physician's Follow Up Form for my review. I understand that I can withdraw from the study at any time. I agree to take part in this study.

Physician's Name

Physician's Signature

Date

Please return both pages of this form to:

CI Pharma Inc.
246 Matheson Blvd East
Mississauga, ON L4Z 1X1

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