



**GYNECOLOGIC ONCOLOGY GROUP/AMERICAN COLLEGE
OF RADIOLOGY IMAGING NETWORK**

GOG-0233/ACRIN 6671

**UTILITY OF PREOPERATIVE FDG-PET/CT SCANNING PRIOR TO
PRIMARY CHEMORADIATION THERAPY TO DETECT
RETROPERITONEAL LYMPH NODE METASTASIS IN PATIENTS
WITH LOCOREGIONALLY ADVANCED CARCINOMA OF THE
CERVIX (IB2, 11A \geq 4 CM, IIB-IVA) OR ENDOMETRIUM (GRADE 3
ENDOMETRIOID ENDOMETRIAL CARCINOMA; SEROUS PAPILLARY
CARCINOMA, CLEAR CELL CARCINOMA, OR CARCINOSARCOMA
(ANY GRADE); AND GRADE 1 OR 2 ENDOMETRIOID ENDOMETRIAL
CARCINOMA WITH CERVICAL STROMAL INVOLVEMENT OVERT
IN CLINICAL EXAMINATION OR CONFIRMED BY ENDOCERVICAL
CURETTAGE)**

(11/16/09)

PET/CT Imaging:

Participants must undergo whole-body PET and CT imaging with a PET/CT unit per institutional standard of care. ***Reminder for PET imaging: All PET exams should contain three trans-axial whole body series, attenuated and non-attenuated corrected PET scans, and the CT images.** The PET/CT unit should have a multi-slice CT (>1 slice) and BGO (Bismuth Germinate Oxide), LSO (Lutetium Oxyorthosilicate) or GSO only. Sodium Iodide (NaI) based scanners are not acceptable. The ability to calculate standardized uptake value (SUV) is also mandatory. The PET/CT scanner needs to be qualified by ACRIN before participating in this protocol.

Detailed information can be found on the ACRIN web site at:

<http://www.acrin.org/PROTOCOLSUMMARYTABLE/PROTOCOL6671/6671ImagingMaterials/tabid/417/Default.aspx> under ACRIN 6671/GOG 0233 Imaging Materials.

PET Technical Assessment Form will be used to ensure protocol compliance. The PET Technical Assessment Form can be found on the ACRIN web site at:

<http://www.acrin.org/PROTOCOLSUMMARYTABLE/PROTOCOL6671/6671ImagingMaterials/tabid/417/Default.aspx>.

There is no set criterion that requires the original institution to repeat a PET/CT study. However, considering that PET/CT is standard of care for initial staging of cervical and endometrial cancers, the study may be repeated if it is judged by the original institution that the study is suboptimal and does not provide clinical information to stage the patient prior to therapy. The most common reasons that result in a suboptimal study can be found in Form C1.

Participant/FDG Preparation: Please refer to Section 13.0 for detailed drug (FDG) information.

The order of FDG-PET/CT study will be as follows:

- 1 Measure blood glucose level by glucometer. If it is below 150 mg/dL, continue. If blood glucose level is above 150 mg/dL, consult nuclear medicine physician.
- 2 If applicable, place Foley catheter.
- 3 Place an intravenous catheter. Give oral contrast to the participant.
- 4 Inject FDG, and flush catheter with 20-40 mL of normal saline solution. All participants will be well hydrated during the study (typically given an infusion of 500 mL 0.45% or 0.9% saline solution intravenously) or if intravenous hydration is not possible (e.g., if it is difficult to establish intravenous access), must drink a minimum of 4 cups of water.

5 See below (Section 12.1.1) for detailed information about two options for CT acquisition. Approximately 60 minutes (+/- 10 minutes) after FDG injection, a diagnostic CT scan with contrast agents (oral and intravenous) or a low-dose CT (with oral contrast) will be performed. Patients must void prior to imaging. The diagnostic or low-dose CT of the chest, abdomen, and pelvis should be completed 60 minutes (+/- 10 minutes) after FDG injection, if it is performed before PET emission scan. The diagnostic or low-dose CT of the chest, abdomen, and pelvis should be initiated immediately after PET emission scan, if it is performed after PET emission scan. In either case, **the PET emission scan has to be performed approximately 60 minutes (+/- 10 minutes) after FDG injection.**

6 PET emission scan will be performed immediately after a low-dose CT or after the diagnostic CT depending on the CT option. At some sites, the diagnostic CT will be taken immediately after PET imaging without moving the patient (see options described in Section 12.1.1 below). Per one of the CT protocols described in Section 12.1.1 below, some centers may perform a second CT scan only for attenuation correction of the PET images. Thus, a second low-energy CT scan can be performed just prior to emission PET scan (after completion of a diagnostic CT) for attenuation correction of the PET images. In the alternative scenario described below, the low-dose CT scan must be performed prior to the PET scan if the diagnostic CT is to follow the PET imaging. The CT parameters for attenuation correction will be utilized according to imaging protocol at each center. We recommend effective mAs of 111, kVp of 130, 5-mm slice thickness and 4-mm interval

Diagnostic CT Imaging:

General: All PET/CT (including the diagnostic CT part of PET/CT) scans must be performed on the same scanner immediately before or after the PET emission scan, depending on the CT option (see below). In either case, **the PET emission scan has to be performed approximately 60 minutes (+/- 10 minutes) after FDG injection.** It is recommended (but not obligatory) to use a breathing technique already in place to diminish respiratory artifacts. Typically, participants will be instructed to hold their breath while scanning the diaphragm.

1 *First option:* Diagnostic CT before PET (with optional low-dose CT in between). Diagnostic CT imaging (with oral and intravenous contrast) per institutional standard of care will be done approximately 60 minutes (+/- 10 minutes) after the FDG injection (see Section 12.1.4) beginning in a craniocaudal direction with the participant's upper neck. An optional low-dose CT can be conducted immediately after the diagnostic CT without moving the participant. The low-dose CT will take a minute or so.

2 The PET scan should follow immediately after the CT without moving the

participant.

Second option: The low-dose CT (with oral contrast) will be performed before PET emission scan and the diagnostic CT will be performed immediately after completion of PET emission scan.

1 The low-dose CT, starting at approximately 60 minutes (+/- 10 minutes) after FDG injection immediately before the PET emission scan in a craniocaudal direction starting with the participant's upper neck. The low-dose CT will take a minute or so.

2 The PET emission scan should then be initiated at 60 minutes (+/- 10 minutes) immediately after the low-dose CT scan.

3 Diagnostic (intravenous contrast) CT should be performed immediately after the PET scan without moving the participant (it will be about 75 to 90 minutes after the FDG injection).

Intravenous contrast: Intravenous contrast is required in participants with adequate intravenous access and no contradictions to it. A nonionic contrast agent (such as Optiray 350) will be administered intravenously according to the participant's weight:

For participants <180 pounds, 125 mL of Optiray[®] 350 (Mallinckrodt Inc.) or equivalent will be given at the rate of 3 mL/sec with a 55-sec delay in imaging.

For participants ≥180 to <250 pounds, 150 mL Optiray 350 will be given at the rate of 3 mL/sec with a 70-sec delay in imaging.

For participants 250 to 300 pounds, 175 mL Optiray 350 will be given at the rate of 3 mL/sec with an 85-sec delay in imaging.

Oral contrast: A water-soluble, iodinated oral contrast such as MD-Gastroview[®] (Mallinckrodt Inc.) or equivalent is preferred over barium. Typically, a total dose of 600 mL of MD-Gastroview will be ingested prior to FDG injection.

MD-Gastroview (Diatrizoate Meglumine and Diatrizoate Sodium Solution) is a palatable lemon-vanilla flavored water-soluble iodinated radiopaque contrast medium for oral or rectal administration. Each mL contains 660 mg diatrizoate meglumine, 100 mg diatrizoate sodium, and approximately 4.8 mg sodium and 367 mg organically bound iodine. MD-Gastroview will be prepared according to the package insert – 25 ml of MD-Gastroview is diluted in 1L of tap water. A 600 mL dose is equal to 22.9 g of iodine.

PET Imaging:

All participants will begin fasting 4 hours prior to the FDG PET/CT imaging. If the participant is receiving total parenteral nutrition and/or

intravenous fluids containing glucose, it also should be discontinued for at least 4 hours prior to the FDG-PET imaging. To exclude fasting hyperglycemia in all participants regardless of history of diabetes or nutritional status (such as total parenteral nutrition), the blood glucose level should be determined prior to the FDG administration. No diabetic medications should be administered within 4 hours prior to checking the glucose level. Participants with poorly controlled diabetes can have a small dose of short-acting insulin (with dose determined by the referring physician) with a light meal and then fast for 4 hours prior to the PET study. PET imaging should not be performed if the blood glucose level is >200 mg/dL.

An intravenous catheter (typically, a 20- or 22-gauge Angiocath) will be placed, typically in the antecubital fossa, for participant hydration, contrast, and FDG administration. 10-20 mCi of FDG (0.14-0.21 mCi/kg) will be administered intravenously as a bolus. A dose at a higher end of the range is recommended, with appropriate reduction in the per kilogram dose for heavier patients (in accordance with the manufacturer's recommendation). All participants will be well hydrated during the study (typically given an infusion of 500 mL 0.45% or 0.9% saline solution intravenously) or a minimum of 4 cups of water, if intravenous hydration is not possible (e.g., if it is difficult to establish intravenous access). To ensure adequate clearance of bladder activity (which might obscure structures adjacent to the bladder), all participants should void immediately prior to imaging.

Optional Diuretic Treatment: *Diuretics without Foley catheter:* 20 mg of furosemide will be given before or at the time of FDG administration.

Diuretic with Foley catheter: 20 mg of furosemide will be given 20 minutes after FDG administration. Before the study, a Foley catheter (typically 16-french) will be placed using aseptic technique.

PET Technique:

Imaging will begin approximately 60 minutes (+/- 10 minutes) after FDG injection (see above in Section 12.1.1 for the order options of diagnostic and low-dose CT and PET imaging). The participant will be positioned supine, with arms comfortably positioned above the head, whenever possible. To minimize lower back discomfort, one or two pillows may be placed under the participant's knees. The region imaged should extend from the participant's upper/mid-neck to the upper thigh.

If the acquisition of diagnostic CT data (see Section 12.1.1 for CT

technique) occurs prior to PET imaging, the imaging table will automatically be moved further into the imaging system and PET imaging will be initiated, covering the same field of view as the CT, beginning in a caudocranial direction with the participant's upper thigh. A series of sequential emission scans (3–5 minutes' duration, depending on the participant's size) will be performed. Images will be corrected for scatter and reconstructed using iterative reconstruction algorithm. Emission PET images will be reconstructed with and without attenuation data. Low-dose and/or diagnostic CT data will be used for attenuation correction of the PET data per the options outlined in Section 12.1.1 above. Image reconstruction will depend on the scanner manufacturer. We recommend an iterative reconstruction using OSEM algorithm in a 128 x 128 matrix with a Zoom of 1 and with a 5 mm Gaussian filter. Scatter, decay and deadtime correction, as provided by the manufacturer.

GOG 0233/ACRIN 6671 PET/CT Imaging Options

