Statistical Analysis Plan (SAP)

Translational Development of Photon Counting CT

Principal Investigator Elizabeth Jones, MD

Chief, Radiology

Clinical Center, NIH

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Abbreviations

CT	Computed Tomography
PCCT	Photon Counting Computed Tomography

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1. Introduction

The aim of the protocol is to perform clinical imaging with a new type of CT detector technology using a prototype Photon Counting CT scanner fitted with photon counting detectors (PCCT) in order to generate hypotheses for testing the diagnostic value of this scanner in specific clinical disease states and provide NIH expert opinion and ongoing feedback on scanner performance to the manufacturer developing the scanner as part of a cooperative research and development agreement.

2. Study Design

Study subjects will be recruited from the group of patients on other clinical research protocols at the Clinical Center who have been referred to Radiology for a clinical CT scan as part of their clinical protocol. The patients may have a variety of histories studied at the Clinical Center including but not limited to inflammatory disease of the lungs, body or cancers of the chest, lung, genitourinary system, vascular diseases or metabolic bone disease.

The PCCT scans are either identical in extent, or more often are individualized to cover a smaller area including a specific area of interest, than the clinically indicated CT scans. The clinically indicated scans are reviewed and reported separately as per standard clinical care. Experienced radiologists will review the PCCT images using the clinical application Carestream VuePACS at clinical workstations in conditions comparable to the normal reading environment. Images from PCCT and conventional CT from patients who successfully complete the PCCT component of their scan will be evaluated for diagnostic image quality.

2.1 Sample Size

A power calculation could not be performed because this is an exploratory study. The technology is still under development and the clinical utility and potential applications are uncertain. Based on prior studies showing equivalence between PCCT and conventional CT images performed in normal volunteers, patient in various disease states will be studied.

3. Aims and Objectives

To perform imaging with the prototype scanner on patients with clinical diseases to evaluate image quality.

4. Outcomes

4.1 Primary outcome

Mean difference in relative image quality grading of CT images using Photon counting detectors compared to conventional detectors in group of patients with various clinical conditions.

4.2 Safety Outcomes

Adverse events related to the scanner are not anticipated but will be reported as outlined in the protocol.

5.0 Populations and subgroups

5.1 Population

All enrolled participants who complete the PCCT scan.

5.2 Subgroups

Potential subgroups will be established if sufficient number of patients with specific diagnoses are accrued.

6.0 Analysis

6.1 Primary Outcome

Mean difference in relative image quality grading of CT images using Photon counting detectors vs. conventional detectors in group of patients with various clinical conditions.

Expert radiologist observers compare the relative grading of the images from the PCCT to the grading of the same patient's reference images from conventional CT acquired at the same time. They will use the method termed "Visual grading analysis (VGA)" . The visual grading scale incorporates technical factors in the acquisition and image display (such as contrast, noise and presence of artifacts and post processing). Grading is based on 5-point scale. 1- lowest image quality, 5- highest image quality. 5 is a better result. Scale as follows: 1 Images not usable- severe limitations for diagnostic use, 2 Limited -some loss of information, significant limitations for clinical use, 3 Adequate -moderate limitations for diagnostic use, 4 Good-minimal limitations for clinical use, 5 Excellent- no limitations for clinical diagnosis.

The mean difference and standard deviation of the group will be reported.

7.0 Missing data

If PCCT data is incomplete, or not performed, the data will not be included.