

3.10 Computed Tomography (CT) /Electron Beam Computed Tomography (EBCT)

I. BACKGROUND AND GOALS

1. The Multiethnic Study of Atherosclerosis (MESA) is studying risk factors and measures of cardiovascular disease that relate to progression of subclinical to clinical disease. An integral part of this study is the measurement of coronary artery calcium using either electron beam computed tomography (EBCT) or helical computed tomography (HCT). Coronary calcium will be assessed in relation to the risk of future cardiac events, and from repeated scans in selected individuals, the progression of coronary calcium will be related to baseline risk factors and risk of future events.
2. Approximately 6,500 participants will be scanned among the 6 centers during the initial (2-year) examination occurring between July 2000 and June 2002. A sample of about half of participants will receive repeated scans during three subsequent, follow-up examinations in future years.
3. Goals
 - 3.1 To examine the relation of baseline measures of coronary calcium quantity (score and volume measures) to future risk of cardiac events
 - 3.2 To examine the relation of baseline measures of coronary calcium to other risk factors and measures of subclinical disease (e.g., MRI and ultrasound measures).
 - 3.3 To examine the relation of progression of coronary calcium to the risk of future cardiac events, as well as to risk factors at baseline and progression of risk factors.
 - 3.4 To examine the above goals by ethnic and gender strata, when possible.

II. QUALIFICATIONS OF PERSONNEL

1. Field Center personnel will be responsible only for escorting participants to and from the CT scanning site and for making sure that the CT Completion Form is completed by the scanning technologist.
2. Each Field Center has a designated radiologist or cardiologist who is responsible for the performance of the CT examinations at his/her MESA Field Center. This physician should monitor the study closely to ensure adherence to the CT protocol, including following the approved scanning procedures, data transmission, and maintenance of appropriate quality control procedures. They should also supervise each technologist and provide necessary on-site training, supplementing that provided by the CT Reading Center personnel.

3. Field Center technologists should have appropriate knowledge of cross-sectional anatomy, physiology, and pathology related to the heart. Technologists must be certified as RTs in their state. It is recommend that technologists also have at least two years of experience in chest computed tomography. The technologist should also have a basic knowledge of cardiac CT, knowledge of computer software applications, data formatting, and experience with the workstations and data formatting / transmission procedures used.
4. Each technologist involved in the study should also have a complete understanding of this protocol, be experienced at providing breath-holding instruction, ECG gating, operation of the EBCT or HCT equipment. To ensure quality control, each Field Center should have designated CT technicians who will perform the MESA examinations, once appropriate training, including the March 2000 training course, has been provided.

III. PARTICIPANT SCHEDULING

1. The MESA operations committee will arrange details of scheduling, Each scanning site will provide their local Field Center with the days/times when MESA participants may be scheduled and the Field Center will contact participants to arranging their appointments for their CT scan. Whether certain days/times will be held for MESA participants only, until 2 weeks or a certain amount of time prior to the day of the appointment, will be agreed upon between the scanning center and Field Center.
2. A Field Center interviewer/scheduler will be responsible for explaining and obtaining consent for the CT examination. Participants will be scheduled for a certain date and time, and transportation arrangements, if necessary, will be arranged by the Field Center interviewer/scheduler. A confirmation appointment letter will be sent, providing the time, date, and directions to the scanning center, and describing the procedure
3. The scanning procedure, consisting of two scans done in succession on each subject, will require approximately 20 minutes of the subject's time. Minimal respiratory motion and maximum accuracy and reproducibility require this duration. In unusual cases, this may require as many as 30 minutes. In many cases, the procedure will be completed in 15 minutes or less.
4. Please refer to site-specific instructions for escorting participants to and from the scanning site.

IV. COMPLETING THE CT COMPLETION FORM

1. The CT Completion form must be filled out by either the CT technologist or the attending Field Center staff member. If the Field Center staff member completes the form, he/she will need to get information from the CT

technologist before leaving the scan area. The form will be taken back to the clinic and scanned into the computer along with the other forms.

1.1 Question 1: Results of CT scan.

- Complete: Select this response if the scan was complete or partially complete and a file containing the scan data will be sent to the CT Reading Center.
- Incomplete: Select this response if the scan was only partially completed due to a technical or participant problem.
- If Incomplete is selected, indicate whether a file containing this exam information will be sent to the Reading Center. If the scan was Complete or Not Done, leave this question blank.
- Not Done: Select this response if the scan was not even started, due to a technical or participant problem.
- If Incomplete or Not Done is selected, indicate the reason the scan was not completed. If the scan was complete, leave this question blank.

1.2 Question 2 is a comments section.

V. READING CENTER ALERTS

The Reading Center will review all scans within two weeks and will indicate any alerts. A cardiologist or radiologist investigator will review all scans and will identify eventual alerts. The investigator will telephone the CT investigator at the field site and the coordinating center and will write a letter (see CT Manual of Operations) with copies to both. Pathological findings constituting alerts will include pulmonary infiltrates, pericardial or pleural effusions, tumors, dilatation of the aorta greater than 4 cm and pathological rib fractures.