March 20, 2008

Anc 214 A prospective Study of Pancreatic Cancer Pathogenesis in the WHI Observation Study

Case selection:

The pancreatic cancer cases occurred through August 27, 2007. Exclusion criteria include baseline history of any type of cancer except non-melanoma skin cancer, no availability of adequate red blood cell sample, DNA sample, plasma EDTA sample, or participant refused genetic studies.

Central adjudication for all pancreatic cancer cases is finished. As of August 27, 2007, 215 cases of pancreatic cancer occurred in OS cohort were centrally adjudicated. Six cases were excluded because of the histology. Twenty-eight cases were excluded for plasma marker and red blood cells analysis due to baseline history of cancer. Fifteen breast cancers, 3 colorectal cancers, 3 endometrial cancer, 2 melanoma cancer, 2 lymphoma cancer, 1 thyroid cancer 1 other, and 1 missing data. Cases with baseline history of cancer will be eligible for SNP analysis.

All 181 cases have enough red blood cells. Five cases do not have enough EDTA plasma. So the number of cases for plasma marker analysis is 176. Cases with baseline history of cancer will be eligible for SNP analysis. Four out of 209 does not have enough DNA sample. The number of cases is 205 for DNA.

There were 104 locally confirmed cases in Ancillary Study #146. Ninety-two out of 104 were also centrally confirmed and can be used as cases for study #214. Therefore, there are 117 new cases need matched controls.

Control selection:

Control selection was done in a time-forward manner, selecting two controls for each case from the risk set at the time of the case's event. Matching criteria are listed below. The same exclusion criteria listed above for cases also applies to the potential controls with two modifications. Controls may not have had a diagnosis of cancer (except non-melanoma skin cancer) up to the time of the case's diagnosis date. Controls may not be cases for primary outcomes (CHD, stroke, hip fracture, breast cancer, and colorectal cancer) for WHI studies. All controls have enough red blood cells, DNA and EDTA plasma. The total number of eligible controls was 67,183.

Matching criteria:

Matching was done on year of birth, smoking status (never, former, current, missing), fasting status (fasting, non-fasting/missing fasting status), and month of blood draw. Smoking and fasting status were matched exactly. Fasting was defined as at least 8 hours since last ate. Matching windows were not set for year of birth or month of blood draw.

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Instead, the matching algorithm was allowed to select the closest match based on criteria to minimize an overall distance measure (Bergstralh EJ, Kosanke JL. Computerized matching of cases to controls. Technical Report #56, Department of Health Sciences Research, Mayo Clinic, Rochester MN. April 1995). SAS code was available to implement this matching scheme.

Matching results/summary:

Two controls meeting the matching criteria were matched to each of the 117 new cases, resulting in a total of 234 controls. By design, smoking and fasting status matched exactly. For all cases, the matching algorithm also found exact matches for month of blood draw for both controls in each case/control set. For four cases, there is one year difference for year of birth between cases and controls

For 92 cases from Ancillary study #146, two controls were randomly picked from three controls selected for Anc #146.

Total number for Ancillary Study #214 is 181 cases/418 controls for red blood cells analysis, 176 cases /418 controls for plasma marker analysis, and 205 cases/418 controls for DNA analysis.