

Case-Control Selection for AS284

Obesity-related pathways and risk of benign proliferative breast disease (BPBD)

Eligible population /Exclusion criteria

Eligible cases included all women who were diagnosed with incident BPBD during follow-up in the WHI-CT. BPBD diagnosis was based on the histological review conducted for AS130.

Controls include all CT women. When matched to a case, the control did not develop breast cancer, did not develop BPBD, and did not have an abnormal mammogram or clinical breast exam during the same follow-up period as that for the corresponding case. Abnormal mammograms are defined as those for which the summary report of Form 85 is not marked negative for either the right or left breast. Abnormal clinical breast exams are defined as those in which at least one response to at least one item 7.1-7.4 on Form 84 is not no. Women who developed breast cancer or BPBD or had an abnormal mammogram or clinical breast exam were eligible for selection as a control provided the event occurred after the date of BPBD diagnosis for the corresponding case.

Case /control selection

Initially 700 cases were selected by Tom Rohan. Serum samples were not available for 34 of these, so an additional 34 were selected at random from the remaining BPBD cases. For these 666 cases selected by Tom Rohan and the 34 randomly selected cases, matching controls were not available for 10. Thus 10 additional cases were randomly selected from the BPBD cases with available serum.

Controls were selected from eligible participants using risk-set sampling with replacement. Controls were individually matched to corresponding cases on age at baseline with 2 years, race, intervention/non-intervention or not randomized groups of the CT, CM, and CaD, and date of baseline blood draw within 1 year.

Two controls were matched to 690 cases. For 10 cases, only one control could be matched. Then an additional five cases were also selected with one matching control. Due to the sampling with replacement scheme, 23 controls were selected for two different cases. Also, five participants selected as cases were selected as controls for other cases with earlier BPBD diagnosis dates.