

Case-Control Selection for AS271: Omega-3, Omega-6 Fatty Acids as a Biomarker of Hip Fracture Risk

Eligible population /Exclusion criteria

Eligible cases included all women with incident hip fracture as of August 15, 2008 who did not meet any of the following exclusion criteria. Potential controls included all women who had not experienced hip fracture as of August 15, 2008 and who did not meet any of the exclusion criteria.

Women who used bisphosphonates, selective estrogen receptor modulators or other bone-active medications (including calcitonin, raloxifene, tamoxifen, and teriparatide) at baseline were excluded. Women who did not have at least 0.2 mL of stored RBCs available were excluded. Unless enrolled in the HT, women who did not report hormone use at baseline were also excluded.

Case /control selection

A total of 202 women with incident hip fractures in the BMD cohort did not meet any of the above exclusion criteria. These included 70 women from the CT (27 from the HT trial) and 132 women from the OS. One case from the HT trial did not have a matching control and was therefore excluded.

The remaining 199 cases were selected from OS women with incident hip fractures. Of these, 190 were matched to controls selected for BAA 03. The remaining 9 were matched to OS controls not selected for BAA03.

Case and controls were matched by age within +/- 5 years, ethnicity, geographic region by latitude, HT trial arm or self-reported hormone use at baseline, and enrollment in CT or OS. Controls were required to have as long or longer follow-up time than the cases. 306 of the 400 case/controls pairs reported the same age at screening and exact matching on all other matching criteria.

Matching summary

| | Matching criteria | Number of matched cases and controls |
|--|---|---|
| BMD cohort, HT trial | Age, ethnicity, latitude region, HRT arm | 18 pairs with controls also selected for BAA 03 8 pairs with other HT trial controls |
| BMD cohort, CT other than HT trial or OS | Age, ethnicity, latitude region, self-reported hormone use at baseline, OS/CT | 175 |
| OS cohort | Age, ethnicity, latitude region, self-reported hormone use at baseline | 178 pairs with controls also selected for BAA 03 and BAA 18 12 pairs with controls selected for BAA 03 9 pairs with other OS controls |
| Totals | | 400 |