Evidence Table 159. KQ3—Dichotomous—Withdrawal due to adverse events

| **Author Year**  **Study Design** | **Definition of outcome (if relevant)** | **CHD Risk Category** | **CVD drug**  **(dose mg/d))** | **Group 1: Name (supplement)** | **N1** | **N1 with event** | **Group 2: Name** | **N2** | **N2 with event** | **Estimates of Group Differences** | **Additional comments** | **Overall Risk of Bias (ROB) Assessment** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bays 20106  Parallel | N/A | Unclear | Atorvastatin (10-40) | Omega-3 | 123 | 8 | Placebo | 122 | 6 |  |  | Medium |
| Ferraro 200922  Parallel | N/A | Unclear | Ramipril (10) | Omega-3 | 15 | 0 | No Treatment | 15 | 0 |  |  | Medium |
| Mabuchi 200739  Parallel | N/A | Unclear | Atorvastatin (10) | Co-Q10 |  |  | Placebo |  |  |  | "There were no serious adverse events". Data not reported. | Medium |
| Gardner 200723  Parallel | N/A | Mixed: Moderate to high | ASA (325) | Ginkgo biloba |  | 3 | Placebo |  | 2 |  |  | Low |
| Young 200770  Parallel | N/A | Mixed:  Moderate and high risk | Simvastatin (10 - 40) | Co-Q10 |  | 6 | Placebo |  | 4 |  |  | Medium |
| Davidson 200714  Parallel | N/A | Unclear | Simvastatin (40) | Omega-3 | 122 | 3 | Placebo | 132 | 3 |  | no description | Medium |
| D’Arcangues 200413  Parallel | discontinuation due to side effects of treatment | Mixed: Low and/or Moderate | ASA (80) | Vitamin E | 121 | 30 | No Treatment | 122 | 19 |  | Treatment course was for 10 days. But followup went on for up to 1 year. | Medium |
| Nordøy 200054  Parallel | N/A | Mixed: Low and/or Moderate | Simvastatin (20) | Omega-3 | 21 | 0 | Placebo | 20 | 0 |  |  | Medium |
| Garg 199524  Parallel | N/A | At high risk for CHD | ASA and/or pentoxiphylline (20) | Ginkgo biloba | 29 | 0 | Placebo | 26 | 0 |  |  | Medium-high |
| Paolissa 199257  Parallel | N/A | Unclear | Hydrochlorthiazide (25) | Magnesium | 9 | 0 | Placebo | 9 | 0 |  |  | Medium |
| Kaul 199234  Parallel | GI intolerance-- stopped capsules of fish oil | At high risk for CHD | Calcium channel blocker, ASA (NR) | Omega-3 | 58 | 2 | No Treatment | 49 | 0 |  |  | Low-medium |

Evidence Table 159. KQ3—Dichotomous—Withdrawal due to adverse events (continued)

| **Author Year**  **Study Design** | **Definition of outcome (if relevant)** | **CHD Risk Category** | **CVD drug**  **(dose mg/d))** | **Group 1: Name (supplement)** | **N1** | **N1 with event** | **Group 2: Name** | **N2** | **N2 with event** | **Estimates of Group Differences** | **Additional comments** | **Overall Risk of Bias (ROB) Assessment** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nordøy 200355  Parallel | N/A | Mixed: Moderate and high risk | Atorvastatin (10) | Omega-3 | 22 | 0 | Placebo | 20 | 0 |  |  | Low |
| Roth 200960  Parallel | N/A | Unclear | Fenofibrate (130) | Omega-3 | 84 | 4 | Placebo | 83 | 4 |  |  | Medium |
| Isley 200731  Parallel | N/A | Unclear | Niacin (500); ASA (325) | Omega-3 | 8 |  | No Treatment | 7 |  |  |  | Medium |
| Bender 19988  Parallel | N/A | Unclear | Warfarin ( NR) | Omega-3 | 6 | 0 | No Treatment | 5 | 0 |  |  | High |
| Chan 200212  Parallel | N/A | At moderate/moderately high risk for CHD (2+ risk factors) | Atorvastatin (40) | Omega-3 | 11 | 0 | No Treatment | 13 | 0 |  |  | Medium |
| Playford 200358  Parallel | N/A | At high risk for CHD | Fenofibrate (200) | Co-Q10 | 18 |  | No Treatment | 17 |  |  |  | Low-medium |
| Abdul 20101  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Warfarin (25 single dose) | Echinacea | 12 | 0 | No Treatment | 12 | 0 |  |  | Medium |
| Gosai 200826  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Rosuvastatin (40) | Omega-3 | 48 | 2 | No Treatment | 48 | 4 |  |  | Medium |
| Di Spirito 200819  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Atorvastatin (80) | Omega-3 | 50 | 1 | No Treatment | 50 | 0 |  | This one is the same patient who had an elevated CK | Medium |
| Maki 200841  Crossover | N/A | Mixed:  Low, Moderate and high risk | Simvastatin (20) | Omega-3 |  | 2 | Placebo |  | 1 |  |  | Medium |
| McKenney 200645  Crossover | N/A | Mixed:  Low and/or Moderate | Simvastatin (80) | Omega-3 | 24 | 1 | No Treatment | 24 | 0 |  |  | Medium |

Evidence Table 159. KQ3—Dichotomous—Withdrawal due to adverse events (continued)

| **Author Year**  **Study Design** | **Definition of outcome (if relevant)** | **CHD Risk Category** | **CVD drug**  **(dose mg/d))** | **Group 1: Name (supplement)** | **N1** | **N1 with event** | **Group 2: Name** | **N2** | **N2 with event** | **Estimates of Group Differences** | **Additional comments** | **Overall Risk of Bias (ROB) Assessment** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Jiang 200532  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Warfarin (25 single dose) | Gingko biloba |  | 0 | No Treatment |  | 0 |  |  | Medium |
| Jiang 200433  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Warfarin (25 single dose) | Ginseng |  | 0 | No Treatment |  | 0 |  |  | Medium |
| Mauro 200343  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Digoxin (0.5 single dose) | Gingko biloba |  | 0 | No Treatment |  | 0 |  |  | Medium |
| Balestrieri 19964  Crossover | N/A | Mixed:  Low and/or mod to high risk | Simvastatin (10 to 40) | Omega-3 | 16 | 1 | Placebo | 16 | 1 |  | Two patients (one in each group) interrupted the study in the first month. One suffered from acute myocardial infarction, another one underwent a resection of abdominal aortic aneurysm. | Medium |
| Paolissa 199256  Crossover | N/A | At high risk for CHD | Nifedipine (88) | Vitamin E |  | 0 | Placebo |  | 0 |  |  | Medium |
| Mueller 199151  Crossover | N/A | Mixed:  Low and/or Moderate | ASA (325 single dose) | Omega-3 |  | 0 | Placebo |  | 0 |  |  | Medium |
| Wirell 199467  Crossover | N/A | Unclear | metoprolol, atenolol, pindolol & propanolol (NR) | Magnesium | 19 |  | Placebo | 20 | 0 |  |  | Medium |
| Avogaro 19743  Crossover | N/A | Unclear | Propranolol (20 or 60) | Niacin | 10 | 0 | No Treatment | 10 | 1 |  |  | High |