Evidence Table 115. KQ3—Dichotomous—Alanine transaminase (ALT) (raised)

| **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 |  | Unclear | Atorvastatin (10-40) | Omega-3 |  | NR | Placebo |  | NR | NR |  | Medium |
| Young 200770  Parallel | > 3 times the upper level of normal | Mixed:  Mod and high risk | Simvastatin (10-40) | Co-Q10 | 22 | 1 | Placebo | 22 | 1 | NR | Exclusion criteria included: alanine aminotransferase or aspartate aminotransferase > 3 times the upper level of normal and results state: "Liver... function, …[was] not altered with either regime." Thus, counts of 0 and 0 were added for each arm | Medium |
| Davidson 200714  Parallel | mild elevation of ALT | Unclear | Simvastatin (40) | Omega-3 | 122 | 0 | Placebo | 132 | 0 | NR | p=NS | Medium |
| Davidson 200714  Parallel | ALT >3.0 x ULN | Unclear | Simvastatin (40) | Omega-3 | 122 | 2 | Placebo | 132 | 1 |  | Study reports: no cases of clinically significant increases in hepatic transaminase levels (>3.0 x ULN) in either group. | Medium |

| Evidence Table 115. KQ3—Dichotomous—Alanine transaminase (ALT) (raised) (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** |
| Duffy 200120  Parallel |  | Mixed: Mod and high risk. | Simvastatin (10-40) | Vitamin E | 6 | 0 | No Treatment | 7 | 0 |  |  | Medium |
| Napoli 199852  Parallel | NR | Unclear | Pravastatin (20-40) | Vitamin E |  | 0 | No Treatment |  | 0 |  | “..no differences in routine laboratory tests or adverse events were registered during the study (data not shown); in particular there were no differences between the values recorded in each individual after treatment compared to baseline values, and no differences between the treatment groups.” | Medium |
| Chan 200212  Parallel |  | At moderate/moderately high risk for CHD (2+ risk factors) | Atorvastatin (40) | Omega-3 | 11 | 0 | No Treatment | 13 | 0 |  |  | Medium |
| Liu 200337  Parallel | tested for liver function | Unclear | Simvastatin (10) | Omega-3 | 19 | 0 | No Treatment | 18 | 0 |  |  | Medium |
| Playford 200358  Parallel |  | At high risk for CHD | Fenofibrate (200) | Co-Q10 | 18 | 0 | No Treatment | 17 | 0 |  |  | Low-medium |
| Gosai 200826  Crossover | reference range males: 0-46 U/L; females: 0-36 U/L | At low risk for CHD (0-1 risk factors) | Rosuvastatin (40) | Omega-3 | 48 | 1 | No Treatment | 48 | 4 |  | N/A | Medium |
| Di Spirito 200819  Crossover | N/A | At low risk for CHD (0-1 risk factors) | Atorvastatin (80) | Omega-3 | 50 | 14 | No Treatment | 50 | 13 |  | N/A | Medium |
| Balestrieri 19964  Crossover | N/A | Mixed:  Low and/or mod to high risk | Simvastatin (10-40) | Omega-3 | 14 | 0 | Placebo | 16 | 0 |  | N/A | Medium |
| Paolissa 199256  Crossover | N/A | At high risk for CHD | Nifedipine (88) | Vitamin E |  | 0 | Placebo |  | 0 |  | N/A | Medium |
| Watson 199966  Crossover | N/A | At high risk for CHD | ACE inhibitors (no description), furosemide, digoxin, also hydralazine and/or nitrates (NR) | Co-Q10 |  | 0 | Placebo | 0 | 0 | NR | N/A | Medium |
| Kim 201035  Crossover | N/A | Mixed:  Low and/or Moderate | Ticlopidine (250 –single dose) | Ginkgo biloba | 24 | 0 | No Treatment | 24 | 0 | NR | N/A | Medium |