

Supplemental Table S7. Other liver function test results and self-reported symptoms for eight women whose Alanine aminotransferase (ALT) increased above 300 U/L over the course of treatment with GTE or placebo, The Minnesota Green Tea Trial, 2009-2015

| ID | Group | Row variable | Baseline test | Test 1 | Test 2 | Test 3 | Test 4 | Test 5 | Test 6 | Test 7 | Test 8 | Test 9 | Test 10 | Test 11 | Test 12 | Test 13 | Test 14 | Test 15 | Test 16 | Final status | Comments | | | |
|-----|-------|--------------|---------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|--------------|--------------|--|--|--|
| G09 | GTE | # Days* | 0 | 31 | 62 | 91 | 111 | 129 | 142 | 183 | 274 | 364 | | | | | | | | | Off & Follow | No adverse event or GI symptoms reported. | | |
| | | ALT | 14 | 24 | 23 | 896 | 475† | 119 | 80 | 72 | 28 | 24 | | | | | | | | | | | | |
| | | AST | 20 | 24 | 23 | 697 | 278 | 88 | 56 | 58 | 30 | 26 | | | | | | | | | | | | |
| | | AKP | 70 | 73 | 70 | 161 | 161 | 110 | 91 | 91 | 82 | 76 | | | | | | | | | | | | |
| | | Bilirubin | 0.4 | 0.5 | 0.4 | 0.5 | 0.5 | 0.6 | 0.5 | 0.6 | 0.4 | 0.6 | | | | | | | | | | | | |
| G11 | GTE | # Days* | 0 | 29 | 62 | 91 | 111 | 126 | 168 | | | | | | | | | | | | Withdrawal | No adverse event or GI symptoms reported. | | |
| | | ALT | 12 | 12 | 16 | 483 | 304† | 136 | 38 | | | | | | | | | | | | | | | |
| | | AST | 15 | 15 | 16 | 194 | 105 | 58 | 23 | | | | | | | | | | | | | | | |
| | | AKP | 64 | 58 | 60 | 78 | 78 | 69 | 77 | | | | | | | | | | | | | | | |
| | | Bilirubin | 0.4 | 0.3 | 0.4 | 0.6 | 0.5 | 0.5 | 0.5 | | | | | | | | | | | | | | | |
| G12 | GTE | # Days* | 0 | 31 | 58 | 92 | 112 | 126 | 142 | 199 | 294 | 393 | | | | | | | | | Off & Follow | No adverse event or GI symptoms reported. | | |
| | | ALT | 13 | 10 | 17 | 497 | 351† | 162 | 59 | 26 | 14 | 43 | | | | | | | | | | | | |
| | | AST | 19 | 17 | 23 | 360 | 297 | 120 | 55 | 30 | 19 | 50 | | | | | | | | | | | | |
| | | AKP | 47 | 49 | 50 | 61 | 58 | 54 | 47 | 46 | 42 | 44 | | | | | | | | | | | | |
| | | Bilirubin | 0.4 | 0.5 | 0.6 | 0.7 | 0.7 | 0.7 | 0.5 | 0.8 | 0.6 | 0.6 | | | | | | | | | | | | |
| G17 | GTE | # Days* | 0 | 30 | 61 | 99 | 128 | 147 | 160 | | | | | | | | | | | | Withdrawal | Reported abdominal pain | | |
| | | ALT | 16 | 20 | 22 | 28 | 383 | 399† | 31 | | | | | | | | | | | | | | | |
| | | AST | 19 | 20 | 22 | 22 | 230 | 510 | 21 | | | | | | | | | | | | | | | |
| | | AKP | 83 | 88 | 89 | 99 | 168 | 168 | 128 | | | | | | | | | | | | | | | |
| | | Bilirubin | 0.8 | 0.9 | 0.8 | 0.5 | 0.9 | 2.3 | 0.7 | | | | | | | | | | | | | | | |
| G19 | GTE | # Days* | 0 | 28 | 60 | 95 | 122 | 158 | 188 | 273 | 277 | 387 | | | | | | | | | Withdrawal | Reported increased stress and alcohol intake the day before her elevated liver enzyme blood draw. She has also reported taking Advil and Airborne. | | |
| | | ALT | 16 | 18 | 15 | 15 | 19 | 48 | 70 | 2055 | 1762 | 248 | | | | | | | | | | | | |
| | | AST | 18 | 19 | 19 | 17 | 18 | 27 | 37 | 963 | 848 | NA | | | | | | | | | | | | |
| | | AKP | 53 | 53 | 54 | 53 | 49 | 54 | 52 | 142 | 129 | NA | | | | | | | | | | | | |
| | | Bilirubin | 0.6 | 0.9 | 0.8 | 0.7 | 0.9 | 0.9 | 1.1 | 1.7 | 2.3 | NA | | | | | | | | | | | | |
| G24 | GTE | # Days* | 0 | 39 | 68 | 99 | 130 | 158 | 189 | 221 | 250 | 272 | 300 | 334 | 365 | 379 | 383 | 393 | 417 | | Completed | On her last visit, she reported stomachache when taking the capsules without food; otherwise, taking them with food has been okay. | | |
| | | ALT | 10 | 9 | 10 | 11 | 11 | 1 | 15 | 12 | 11 | 12 | 18 | 13 | 102 | 888† | 1017 | 434 | 72 | | | | | |
| | | AST | 18 | 15 | 16 | 15 | 17 | 16 | 26 | 17 | 19 | 18 | 21 | 20 | 89 | 706 | 651 | 289 | 76 | | | | | |
| | | AKP | 99 | 84 | 97 | 100 | 96 | 98 | 101 | 100 | 94 | 108 | 106 | 101 | 99 | 125 | NA | 158 | NA | | | | | |
| | | Bilirubin | 0.5 | 0.5 | 0.4 | 0.4 | 0.3 | 0.3 | 0.6 | 0.4 | 0.3 | 0.2 | 0.3 | 0.3 | 0.5 | 0.7 | NA | 0.8 | NA | | | | | |
| G30 | GTE | # Days* | 0 | 31 | 56 | 93 | 106 | 118 | 125 | 155 | 174 | 188 | 195 | 209 | 273 | 356 | | | | | Off & Follow | Reported nausea | | |
| | | ALT | 20 | 26 | 22 | 114 | 145† | 74 | 85 | 303 | 253 | 156 | 107 | 59 | 64 | 35 | | | | | | | | |
| | | AST | 12 | 28 | 27 | 87 | 90 | 54 | 72 | 214 | 137 | 99 | 71 | 46 | 48 | 33 | | | | | | | | |
| | | AKP | 38 | 33 | 34 | 47 | 53 | 40 | 44 | 53 | 48 | 46 | 48 | 47 | 43 | 50 | | | | | | | | |
| | | Bilirubin | 0.4 | 0.4 | 0.5 | 0.4 | 0.4 | 0.4 | 0.3 | 0.5 | 0.5 | 0.4 | 0.5 | 0.5 | 0.4 | 0.4 | | | | | | | | |

(Supplemental Table S7 continued)

| New ID | Group | Row variable | Baseline test | Test 1 | Test 2 | Test 3 | Test 4 | Test 5 | Test 6 | Test 7 | Test 8 | Test 9 | Test 10 | Test 11 | Test 12 | Test 13 | Test 14 | Test 15 | Test 16 | Final status | Comments |
|--------|-------|--------------|---------------|--------|--------|--------|--------|--------|--------|--------|--------|-------------------------|------------|---------|------------|-----------|-----------|---------|---------|--------------|---|
| G35 | GTE | # Days* | 0 | 40 | 57 | 90 | 119 | 151 | 181 | 209 | 272 | 291 | 305 | 366 | 385 | 399 | 413 | | | Completed | No adverse event or GI symptoms reported. |
| | | ALT | 18 | 19 | 16 | 15 | 16 | 13 | 22 | 20 | 163 | <i>167</i> [†] | <i>66</i> | 448 | 239 | 126 | 88 | | | | |
| | | AST | 15 | 15 | 16 | 17 | 16 | 15 | 21 | 28 | 82 | <i>67</i> | <i>34</i> | 188 | <i>142</i> | <i>63</i> | <i>49</i> | | | | |
| | | AKP | 41 | 43 | 50 | 49 | 45 | 45 | 43 | 45 | 49 | <i>57</i> | <i>56</i> | 56 | 56 | 48 | 49 | | | | |
| | | Bilirubin | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 | 0.4 | 0.6 | 0.5 | 0.4 | <i>0.6</i> | <i>0.6</i> | 0.7 | 0.7 | 0.4 | 0.6 | | | | |

* Number of days since entry into the study (0 = randomization date)

† Italicized numbers in brown shade were tested during the off-treatment period.

¹ First-time detected ALT > 90 U/L.

² Second-time detected ALT > 90 U/L.

³ Third-time detected ALT > 90 U/L.