Appendix Table C78. Study withdrawals and adverse events (outcomes part D), CCB versus placebo trials

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study Withdrawals, Any, n/N (%)** | **Serious Adverse Event: Any, n/N (%)** | **Serious Adverse Event: Any Leading to Withdrawal, n/N (%)** | **Adverse Event: Any, n/N (%)** | **Adverse Event: Any Specific, n/N (%)** | **Renal Adverse Events: Any, n/N (%)** |
| **CCB** | **Placebo** | **CCB** | **Placebo** | **CCB** | **Placebo** | **CCB** | **Placebo** | **CCB** | **Placebo** | **CCB** | **Placebo** |
| Berl 200360Lewis 200140 | 2/567 (0.4) | 4/569 (0.7) | \*NR | \*NR | †NR | †NR | †NR | †NR | HyperK: 3/567 (0.5) | HyperK: 2/569 (0.4) | ‡NR | ‡NR |
| Crepaldi 199810 | 15/41 (36.6) | 15/49 (30.6) |  |  |  |  | #NR | #NR | #NR | #NR |  |  |

CCB = calcium channel blocker; ARB = angiotensin receptor blocker; HyperK = hyperkalemia
\*Study reported that 61% of participants had at least one serious adverse event but didn’t report results by treatment group (note that study also included an ARB arm).
† Results were not reported for the proportion of study participants with any adverse event, or any serious adverse event leading to withdrawal, either overall or within groups. However, study reported that 51/567 (9.0%) of CCB group and 41/569 (7.2%) of placebo group discontinued treatment due to adverse event.
‡ Study reported one episode of an early increase in serum creatinine concentration suggestive of renal artery stenosis that necessitated stopping the study medication, but did not indicate in which treatment group this adverse event occurred.
# During run-in period, three adverse events resulted in withdrawal from placebo group (two lower limb edema, one hyperkalemia); during randomized study, six adverse events resulted in withdrawal from placebo group (one each herpes zoster, lunge cancer, flaulence, tuberculosis, severe diabetic neuropathy, and myocardial infarction; also reported that 27% of those on CCB and 20% of those on placebo experienced side effects that did not cause withdrawal from study.