Appendix Table C39. Study withdrawals and adverse events (outcomes part D), ACEI plus diuretic versus ACEI plus CCB trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Any Study Withdrawals,**  **n/N (%)** | | **Withdrawals Due to Serious Adverse Events,**  **n/N (%)** | | **Serious Adverse Events,**  **n/N (%)** | | **Adverse Events, Any, n/N (%)** | | **‡Adverse Events, Specific, n/N (%)** | | **Renal Adverse Events, n/N (%)** | |
| **ACEI + Diuretic** | **ACEI + CCB** | **ACEI + Diuretic** | **ACEI + CCB** | **ACEI + Diuretic** | **ACEI + CCB** | **ACEI + Diuretic** | **ACEI + CCB** | **ACEI + Diuretic** | **ACEI + CCB** | **ACEI + Diuretic** | **ACEI + CCB** |
| Bakris, 200847 | \*NR | \*NR | †NR | †NR |  |  |  |  | Edema: 12/166 (7.2); Cough: 17/166 (10.2); Dizzy: 11/166 (6.6) | Edema: 29/166 (17.5); Cough: 23/166 (13.9); Dizzy: 15/166 (9.0) |  |  |
| Bakris, 201048 |  |  |  |  |  |  |  |  | Edema: 85/532 (16.0)  Dizzy: 129/532 (24.2  Cough:  93/532 (17.5)  Hypotension: 29/532 (5.5)  Hyperk:  1/532 (0.2) | Edema:  189/561 (33.7)  Dizzy: 141/561 (25.1))  Cough: 120/561 (21.4)  Hypotension: 24/561 (4.3)  Hyperk: 0/561 (0.0) |  |  |

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker  
\*Study reported 215/453 (47%) withdrawals after randomization overall, including 144/453 (32%) during dose titration period who were considered to be either nonresponders to treatment or had complained of side effects (treatment group not reported) and 71/309 (23%) during study period (36/166 [21.7%] in ACEI + Diuretic group and 26/166 [15.7%] in ACEI + CCB group).  
†Study reported adverse event reasons for study medication discontinuations due to adverse events (18/166 [10.8%] for ACEI + Diuretic group and 9/166 [5.4%] for ACEI + CCB group), but did not report serious adverse events or discontinuations due to serious adverse events.  
‡Study reported additional side effects by treatment group, including: fatigue (13/166 [7.8%] in each treatment group); headache (16/166 [9.6%] in ACEI + Diuretic group and 14/166 [8.4%] in ACEI + CCB group).