Appendix Table C111. Study withdrawals and adverse events (outcomes part D), strict versus standard blood pressure control 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 (%)** |
| **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** |
| Ruggenenti, 200566REIN-2 | 22/169 (13.0) | 30/169 (17.8) | 37/169 (21.9) | 25/169 (14.8) | 6/169 (3.6) | 3/169 (1.8) |  |  | Hyperkalemia 0/169 | Hyperkalemia 0/169 |  |  |
| Wright, 200226AASK | 0/540† | 0/554† |  |  |  |  |  |  | ‡Hyperkalemia: 0/540Cough: 295/540 (54.6)\* | ‡Hyperkalemia: 4/554 (0.7)Cough: 260/554 (47.0) |  |  |
| Schrier 200268 - Study A, Estacio 200067 - Study BABCD |  |  |  |  |  |  |  |  |  |  |  |  |
| Lewis, 199969 | §NR | §NR |  |  | §NR | §NR |  |  | Postural hypotension: 11/63 (17.5)\*Edema: 4/63 (6.3)\*Bronchitis: 2/63 (3.2)\*Sinusitis: 3/63 (4.8)\* | Postural hypotension: 4/66 (6.1)Edema: 10/66 (15.2)Bronchitis: 7/66 (10.6)\*Sinusitis: 13/66 (19.7)\* |  |  |
| Toto, 199570 |  |  |  |  |  |  |  |  |  |  |  |  |
| Peterson, 199571 MDRD, StudyA | #NR | #NR |  |  |  |  |  |  |  |  |  |  |

Appendix Table C111. Study withdrawals and adverse events (outcomes part D), strict versus standard blood pressure control trials (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 (%)** |
| **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** | **Strict Target BP** | **Control Target BP** |
| Shulman, 198974 HDFP |  |  |  |  |  |  |  |  |  |  | \*\*Death due to renal disease: 9/159 (5.7) | \*\*Death due to renal disease: 12/138 (8.7) |

BP = blood pressure; NR = not reported; GFR = glomerular filtration rate
\*p< 0.05
†Study reported no withdrawals, but described 8.1% of subjects with no GFR measurement in the final year of follow-up (n=42/540 and 47/554 from the strict and control target treatment groups, respectively) as not active participants at study end.
‡Study reported additional specific adverse events, all of which were not statistically different in incidence between strict and control target blood pressure treatment groups, including: angioedema (3.5 vs. 5.4%), shortness of breath (48.4 vs. 45.8%), syncope (6.3 vs. 5.2%), dizziness (53.4 vs. 49.0%), lightheadedness (51.2 vs. 49.2%), edema (55.1 vs. 54.2%), and sexual dysfunction (29.6 vs. 27.1%).
§Study reported 21/129 (16.3%) withdrawals overall, including 3 withdrawals for adverse events, but didn’t specify either of these outcomes by treatment group.
#Study reported 11/585 (1.9%) participants lost to followup overall, but did not report results by treatment group.
\*\*Deaths attributed to renal disease were those with ICD codes 580-599, which includes: acute or chronic glomerulonephritis, nephrotic syndrome, acute or chronic renal failure, hydronephrosis, urolithiasis, urethritis, urethral stricture, urinary tract infection, and other disorders of the kidneys and urinary tract.