Appendix Table C16. Study withdrawals and adverse events (outcomes part D), ARB monotherapy trials

| **Study** | **Study Withdrawals: Any** | | **Serious Adverse Event: Any** | | **Serious Adverse Event: Any Leading to Withdrawal** | | **Adverse Event: Any** | | **Adverse Event: Cough** | | **Adverse Event: Hyperkalemia** | | **Renal Adverse Events\*** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ARB** | **Control** | **ARB** | **Control** | **ARB** | **Control** | **ARB** | **Control** | **ARB** | **Control** | **ARB** | **Control** | **ARB** | **Control** |
| ***ARB versus placebo/no treatment trials*** | | | | | | | | | | | | | | |
| Tobe, 201135  TRANSCEND | 236/992  (23.8) | 249/999  (24.9) |  |  |  |  |  |  | 5/992  (0.5) | 1/999  (0.1) | *>5.5 mmol/L*  56/992  (5.6) | *>5.5 mmol/L*  25/999  (2.5) | *Acute dialysis*  1/992  (0.1) | *Acute dialysis*  3/999  (0.3) |
| Makino, 200737 | #NR | #NR |  |  |  |  | NR\* | NR\* |  |  |  |  |  |  |
| Brenner, 200138  RENAAL | 59/751 (7.9) | 59/762 (7.8) |  |  |  |  |  |  |  |  | 8/751 (1.1) | 4/762 (0.5) | 11/751 (1.5) | 9/762 (1.2) |
| Parving, 200139  IRMA-2 | IRB 150mg 27/195 (13.8)  IRB 300mg 20/194 (10.3) | 30/201 (14.9) | § 60/389 (15.4) | 46/201 (22.9) | IRB 150mg 18/195 (9.2)  IRB 300mg 8/194 (4.1) | 17/201 (8.5) |  |  |  |  |  |  |  |  |
| Lewis, 200140  IDNT | 5/579 (0.9) | 4/569 (0.7) | NR‡ | NR‡ |  |  | NR\*\* | NR\*\* |  |  | 11/579 (1.9)† | 2/569 (0.4) | NR†† | NR†† |
| ***ARB versus CCB trials*** | | | | | | | | | | | | | | |
| Saruta, 200941  CASE-J |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Ogawa, 200742 | 0/40 | 2/18  (11.1) |  |  | 0/40 | 0/18 |  |  |  |  |  |  |  |  |
| Lewis, 200140  IDNT | 5/579 (0.9) | 2/567 (0.4) | NR‡ | NR‡ |  |  | NR\*\* | NR\*\* |  |  | 11/579 (1.9)† | 3/567 (0.5) | NR†† | NR†† |

ARB = angiotensin receptor blocker; CCB = calcium channel blocker; NR = not reported  
\* Study reported that “one or more adverse event was recorded in >90% of patients in each treatment group;” no additional adverse events information was provided, including on specific types of adverse events.   
† p < 0.05   
‡ 61% of overall cohort had serious adverse event; results were not provided by treatment group, but were reported to not differ significantly between treatment groups.  
§ Study reported serious adverse events for the two ARB treatment dose groups combined only.  
#Study reported that 13 of 527 (2.4%) randomized participants were excluded from analyses\*\* Results were not reported for the proportion of study participants with any adverse event, either overall or within groups; subjects in the irbesartan group had a significantly lower rate of adverse events per 1000 days of treatment than those in the placebo and amlodipine groups (P=0.002).  
†† 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.